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(74) Agents: DELLENBACH, David et al.; Workman Nydegger, 1000 Eagle Gate Tower, 60 East South Temple, Salt Lake City, UT 84111 (US).

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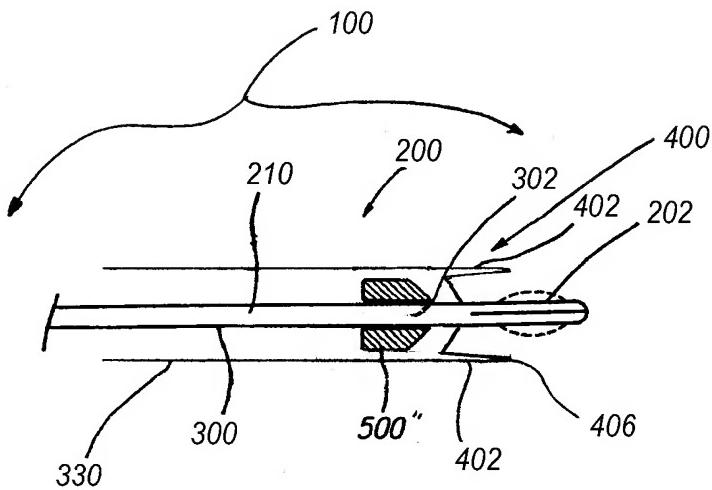
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(71) Applicant (for all designated States except US): AB-BOTT LABORATORIES [US/US]; 100 Abbott Park, Abbott Park, IL 60064 (US).

(72) Inventor; and

(75) Inventor/Applicant (for US only): CARLEY, Micheal, T. [US/US]; 1443 Cerro Verde, San Jose, CA 95120 (US).

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dimension wherein the engaged tissue is drawn substantially closed.

(57) Abstract: An apparatus for delivering and deploying a closure element to an opening formed in a body lumen, including a delivery assembly positionable through the tissue and into the opening. The delivery assembly includes a distal locator portion and a carrier assembly oriented proximal to the distal locator portion. The distal locator portion is configured to selectively engage the body lumen adjacent to the opening, and the carrier assembly is configured to carry and support the closure element in a substantially tubular configuration. The carrier assembly is further configured to urge the closure element toward an expanded cross-sectional dimension for deployment thereof, such that the closure element is oriented to engage the tissue when deployed and, when released, to return to the natural, substantially planar configuration and the natural cross-section

**APPARATUS AND METHOD FOR DELIVERING A CLOSURE ELEMENT****CROSS-REFERENCE TO RELATED APPLICATIONS**

This PCT application claims priority to U.S. Patent Application No. 11/852,190, 5 filed September 7, 2007, entitled “APPARATUS AND METHOD FOR DELIVERING A CLOSURE ELEMENT,” and U.S. Provisional Patent Application No. 60/843,325, filed September 8, 2006, entitled “APPARATUS AND METHOD FOR DELIVERING A CLOSURE ELEMENT,” the disclosure of which is incorporated herein in its entirety by specific reference.

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**BACKGROUND OF THE INVENTION****1. The Field of the Invention**

The present invention relates generally to an apparatus and method for closing and/or sealing openings in a body lumen and/or tissue. More particularly, the present 15 invention relates to an apparatus and method for delivering a closure element for closing a puncture in a blood vessel or other body lumen formed during a diagnostic or therapeutic procedure.

**2. The Relevant Technology**

Catheterization and interventional procedures, such as angioplasty or stenting, are generally performed by inserting a hollow needle through a skin and tissue and into a vascular system. A guide wire may be advanced through the needle and into the blood vessel accessed by the needle. The needle then is removed, enabling an introducer sheath to be advanced over the guide wire into the vessel, e.g., in conjunction with or subsequent 25 to a dilator. A catheter or other device may then be advanced through a lumen of the introducer sheath and over the guide wire into a position for performing a medical procedure. Thus, the introducer sheath may facilitate introducing various devices into the vessel, while minimizing trauma to the vessel wall and/or minimizing blood loss during a procedure.

Upon completing the procedure, the devices and introducer sheath may be removed, leaving a puncture site in the vessel wall. External pressure may be applied to the puncture site until clotting and wound sealing occur. This procedure, however, may be time consuming and expensive, requiring as much as an hour of applied pressure. It is also uncomfortable for the patient, and requires that the patient remain immobilized in the

operating room, catheter lab, or holding area. In addition, a risk of hematoma exists from bleeding before hemostasis occurs.

Various devices have been suggested for percutaneously sealing a vascular puncture by occluding the puncture site. For example, U.S. Pat. Nos. 5,192,302 and 5,222,974, issued to Kensey et al., describe the use of a biodegradable plug that may be delivered through an introducer sheath into a puncture site. Another technique has been suggested that involves percutaneously suturing the puncture site, such as that disclosed in U.S. Pat. No. 5,304,184, issued to Hathaway et al.

To facilitate positioning devices that are percutaneously inserted into a blood vessel, "bleed back" indicators have been suggested. For example, U.S. Pat. No. 5,676,974, issued to Kensey et al., discloses a bleed back lumen intended to facilitate positioning of a biodegradable plug within a puncture site. This device, however, requires that an anchor of the plug be positioned within the vessel, and therefore, may increase the risk of over-advancement of the plug itself into the vessel.

Alternatively, U.S. Pat. No. 5,674,231 issued to Green et al., discloses a deployable loop that may be advanced through a sheath into a vessel. The loop is intended to resiliently expand to engage the inner wall of the vessel, thereby facilitating holding the sheath in a desired location with respect to the vessel.

Accordingly, while these closure devices and procedures are met with varying degrees of success, there is always a need for a new and improved apparatus and technique for delivering a closure element to a vascular puncture site or other opening through tissue.

#### BRIEF SUMMARY OF THE INVENTION

The present invention is directed toward an apparatus and method for delivering a closure element through tissue and into an opening formed in, or adjacent to, a wall of a blood vessel or other body lumen of any size.

In one embodiment, the present invention includes an apparatus for positioning a closure element to close an opening in a body lumen. Such an apparatus includes a carrier assembly and a distal tissue engaging device. The carrier assembly is configured to support a closure element in a substantially tubular configuration in a first diameter. The closure element is configured to substantially uniformly deform from a substantially tubular configuration to a natural, substantially planar configuration. The distal tissue engaging device is selectively axially displaceable relative to at least a portion of the

carrier assembly. As such, the distal tissue engaging device moves between a tissue engaging condition and a tissue closing condition. The tissue engaging condition engages opposing portions of an arterial wall defining said body lumen adjacent to the opening. The tissue closing condition urges the engaged opposing portions of the arterial wall substantially together such that the closure element may be deployed from the delivery assembly to engage the opposed portions of the arterial wall and to return to the natural, substantially planar configuration.

In one embodiment, the distal tissue engaging device includes two or more opposed engaging tongs having respective end tips configured to open radially in directions extending beyond the first diameter to initially engage the opposing portions of the arterial wall, in the engaging condition.

In one embodiment, the carrier assembly further includes a cover member protecting at least the closure element which is contained therein.

In one embodiment, the distal tissue engaging device is integral with a distal end of the cover member.

In one embodiment, the carrier assembly is formed and dimensioned for sliding axial, reciprocating, receipt in a lumen of an introducer sheath extending through said tissue and terminating proximate the opening. The tissue engaging device is configured to cooperate with the introducer sheath to enable movement between the engaging condition and the closing condition.

In one embodiment, the present invention includes an apparatus for delivering and deploying a substantially resilient closure element through tissue to an opening in a body lumen peripherally defined by opposing arterial walls. The closure element is configured to substantially uniformly deform from a natural, substantially resilient planar configuration to a substantially tubular configuration having a substantially natural transverse cross-sectional dimension. The apparatus includes a delivery assembly positionable through the tissue toward the opening in the body lumen. Also, the delivery assembly has a distal tissue engaging device and a carrier assembly configured to support the closure element in the substantially tubular configuration in a first diameter. The distal tissue engaging device is selectively axially displaceable relative to at least a portion of the carrier assembly between a tissue engaging condition and a tissue closing condition. The tissue engaging condition engages the opposing arterial walls of the body lumen adjacent to the opening. The tissue closing condition urges the engaged opposing arterial walls substantially transversely together such that the closure element may be

deployed from the delivery assembly, while substantially maintained in the first diameter, into the opposing arterial walls. The closure element is oriented to engage the engaged opposing arterial walls when deployed and to return to the natural, substantially planar configuration and the natural, transverse cross-sectional dimension such that the engaged 5 opposing arterial walls are drawn substantially closed.

In one embodiment, the apparatus includes a locator configured to position the carrier assembly and distal tissue engaging device adjacent to the opening in the body lumen. Also, the locator has a distal locator portion selectively controllable between an unexpanded state and an expanded state for engaging the opposing portions of the arterial 10 wall of the body lumen.

In one embodiment, the apparatus includes a distal tissue locator portion contained on the delivery assembly. The distal tissue locator portion is configured to facilitate detection of the body lumen and includes one or more expansion elements configured to expand substantially transversely with respect to a longitudinal axis of the distal locator 15 portion.

In one embodiment, the distal locator portion is selectively controllable between an unexpanded state and an expanded state for engaging said opposing arterial walls of said body lumen.

In one embodiment, while in the unexpanded state, the distal locator portion has a 20 transverse cross-sectional dimension less than that of the opening. Also, while in the expanded state, the distal locator portion has a transverse cross-sectional dimension greater than or substantially equal to that of said opening.

In one embodiment, the present invention includes an apparatus for positioning a closure element to close an opening in a body lumen. Such an apparatus includes a 25 carrier assembly and a distal tissue engaging device. The carrier assembly has a tubular body configured to receive a closure element in a substantially tubular configuration in a first diameter prior to deployment. Also, the tubular body has a distal port. The distal tissue engaging device is disposed within the tubular body and is selectively axially displaceable from the distal port. A portion of the distal tissue engaging device is biased 30 to selectively radially extend outwardly from a longitudinal axis of the tubular body to intravascularly engage opposing arterial walls of the body lumen. A portion of the distal tissue engaging device urges the engaged opposing portions of the arterial wall substantially together as the distal tissue engaging device moves proximally. The closure element is then deployed to engage the opposed portions of the arterial wall.

In one embodiment, the carrier assembly includes a cover member defining a lumen configured for slidable receipt of the closure element therein.

In one embodiment, the carrier assembly includes a pusher member that slides for distally deploying the closure element.

5 In one embodiment, the pusher member and the tubular body are disposed as a nested, telescoping tube set with a common longitudinal axis.

In one embodiment, the tubular body includes a tissue locator portion. The tissue locator portion includes a bleed back shaft having a bleed back port distally disposed on a distal end of the tubular body.

10 In one embodiment, the present invention includes a closure system for closing an opening formed in a body lumen peripherally defined by opposing arterial walls. Such a closure system includes a closure element, a delivery assembly, and a pusher member. The closure element is adapted to deform from a natural, substantially resilient planar configuration to a substantially tubular configuration that has a substantially natural 15 transverse cross-sectional dimension. The delivery assembly is capable of being positioned through the tissue and into the opening in the body lumen.

20 Additionally, the delivery assembly has an elongated body, a carrier assembly and a distal tissue engaging device. The carrier assembly includes a carrier seat configured to carry and peripherally support the closure element in the substantially tubular configuration in a first diameter. The distal tissue engaging device is selectively, axially displaceable relative to the carrier seat between an engaging condition and a closing condition. The engaging condition engages the opposing arterial walls of the body lumen adjacent to the opening. The closing condition urges the engaged opposing arterial walls substantially transversely together such that the closure element may be deployed from 25 the carrier assembly, while substantially maintained in the first diameter, into the opposing arterial walls.

30 The pusher member is slidably disposed about the elongated body for relative axial sliding displacement therebetween. The pusher member has a contact portion disposed proximally adjacent to the closure element in order to selectively distally deploy the closure element from the carrier assembly. The closure element is deployed in the substantially tubular configuration so as to engage the opposing arterial walls and to return to the natural, substantially planar configuration and the natural, transverse cross-sectional dimension such that the engaged opposing arterial walls are drawn substantially closed.

In one embodiment, the delivery assembly includes a tubular body supporting the carrier seat. Also, the tubular body defines a central receiving lumen extending longitudinally therethrough that is configured for sliding support of the tissue engaging device for axial movement between the engaging condition and the closing condition.

5 In one embodiment, the pusher member comprises one or more distally extending longitudinal extensions.

In one embodiment, the closure system includes a locator slidably receivable within the pusher member and the delivery assembly.

10 In one embodiment, the present invention includes a method for closing an opening defined by edges of arterial walls of a body lumen. Such a method includes the following: positioning a distal end region of a carrier assembly through tissue adjacent to an opening so that a distal tissue engaging device engages opposing portions of arterial walls, the distal end region of the carrier assembly includes a carrier seat configured to seat said closure element thereon in a substantially tubular configuration, having a first 15 diameter; urging the engaged arterial walls radially inwardly and toward one another such that at least opposed edges of the arterial walls drawn with the first diameter of the closure element; and distally deploying the closure element from the carrier assembly without further substantial radial expansion for the closure element, in the substantially tubular configuration, such that the closure element engages the arterial walls, and returns 20 to the natural, planar configuration and the natural cross-section wherein the tissue is drawn substantially closed.

In one embodiment, the engagement of the arterial walls is performed by extravascularly engaging the arterial walls with the tissue engaging device.

25 In one embodiment, the engagement of the arterial walls is performed by intravascularly engaging the arterial walls with the tissue engaging device.

In one embodiment, the method includes placing a distal end region of a locator portion through tissue into the opening.

In one embodiment, the method includes engaging the arterial walls adjacent to the opening.

30 In one embodiment, the method includes orientating the carrier assembly proximal to the locator portion.

These and other embodiments and features of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of the invention as set forth hereinafter.

**BRIEF DESCRIPTION OF THE DRAWINGS**

To further clarify the above and other advantages and features of the present invention, a more particular description of the invention will be rendered by reference to specific embodiments thereof which are illustrated in the appended drawings. It is  
5 appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope. The invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

FIGURE 1 provides a general illustration of an apparatus for closing openings  
10 formed in blood vessel walls constructed in accordance with the present invention.

FIGURE 2 illustrates one embodiment of a delivery assembly for the apparatus of FIGURE 1.

FIGURE 3A illustrates a top view of one embodiment of a closure element in a natural, planar configuration and with a natural cross-section for use with the apparatus of  
15 FIGURE 1, prior to curing.

FIGURE 3B illustrates a side view of the closure element of FIGURE 3A.

FIGURE 3C illustrates a top view of the closure element of FIGURES 3A-3B after a natural cross-section of the closure element has been reduced, via a curing process.

FIGURE 3D illustrates a side view of the closure element of FIGURE 3C.

FIGURE 3E illustrates a side view of the closure element of FIGURES 3C-3D as the closure element transitions from the natural, planar configuration to a tubular configuration.  
20

FIGURE 3F illustrates a top view of the closure element of FIGURES 3C-3D upon completing the transition from the natural, planar configuration to a substantially  
25 tubular configuration, albeit a natural tubular configuration.

FIGURE 3G illustrates a side view of the closure element of FIGURE 3F.

FIGURE 4A illustrates one embodiment of a distal locator portion and a carrier seat of a carrier assembly of FIGURE 2, both of which are illustrated in an unexpanded state.  
30

FIGURE 4B illustrates the distal locator portion and a carrier seat of FIGURE 4A, both of which are illustrated in an expanded state.

FIGURE 4C illustrates one embodiment of a proximal end region of the delivery assembly of FIGURE 2.

FIGURE 5A illustrates one embodiment of a carrier assembly for the apparatus of FIGURE 1.

FIGURE 5B illustrates one embodiment of a pusher member for the carrier assembly of FIGURE 5A.

5 FIGURE 5C illustrates one embodiment of a cover member for the carrier assembly of FIGURE 5A.

FIGURE 6 illustrates a tube set and the delivery assembly of the apparatus of FIGURE 1 mounted to a handle portion for operative manipulation thereof.

10 FIGURE 7A illustrates the closure element of FIGURES 3A-3G prior to being disposed upon the carrier assembly of FIGURE 5A.

FIGURE 7B illustrates the closure element of FIGURES 3A-3G upon being disposed upon the carrier assembly of FIGURE 5A, and further as the cover member of FIGURE 5C receives the carrier assembly.

15 FIGURE 7C illustrates the closure element of FIGURES 3A-3G being retained substantially within the carrier assembly of FIGURE 5A when the carrier assembly is disposed substantially within the cover member of FIGURE 5C.

FIGURE 8A illustrates a sheath that is positioned through tissue and into an opening formed in a wall of a blood vessel, in one embodiment of the present invention.

20 FIGURE 8B illustrates the locator portion and the carrier assembly of the delivery assembly of the apparatus being advanced distally into the blood vessel.

FIGURE 8C illustrates a distal end region of the locator portion of FIGURE 8B extending into the blood vessel and being transitioned into an expanded state.

25 FIGURE 8D illustrates the distal end region of the locator portion of FIGURE 8C being retracted proximally to engage an inner surface of the blood vessel wall, and the retraction of the sheath to expose the tissue engaging device, in a tissue engaging condition.

FIGURE 8E illustrates engagement of the tissue engaging device of the apparatus of FIGURE 8D with the blood vessel wall.

30 FIGURE 8F illustrates movement of the tissue engaging device from the tissue engaging condition to a closing condition.

FIGURE 8G illustrates the closure element being deployed and engaging tissue adjacent to the opening in the blood vessel wall.

FIGURE 8H illustrates the closure element of FIGURE 8G transitioning from the substantially tubular configuration to the natural, planar configuration while engaging the engaged tissue.

FIGURE 9 is a side elevation view, in cross-section, of another embodiment of the 5 clip applier apparatus having a tissue engaging device deployed from a central lumen of the tubular body, in a tissue engaging condition.

FIGURE 10 is a side elevation view, in cross-section, of the clip applier apparatus of FIGURE 9, illustrating the tissue engaging device in a closing condition.

FIGURE 11 is a side elevation view, in cross-section, of the clip applier apparatus 10 of FIGURE 9, illustrating deployment of the closure element.

FIGURE 12 is a side elevation view, in cross-section, of yet another embodiment of the clip applier apparatus also having a tissue engaging device deployed from a central lumen of the a tubular body, in a tissue engaging condition.

FIGURE 13 is a side elevation view, in cross-section, of the clip applier apparatus 15 of FIGURE 12, illustrating the tissue engaging device in a closing condition.

FIGURE 14 is a side elevation view, in cross-section, of the clip applier apparatus of FIGURE 12, illustrating deployment of the closure element.

FIGURE 15 is a side elevation view, in cross-section, of another embodiment of the clip applier apparatus also having a tissue engaging device deployed from a central 20 lumen of a tubular body, in a tissue closing condition.

## DETAILED DESCRIPTION

While the present invention will be described with reference to a few specific embodiments, the description is illustrative of the invention and is not to be construed as 25 limiting the invention. Various modifications to the present invention can be made to the preferred embodiments by those skilled in the art without departing from the true spirit and scope of the invention as defined by the appended claims. It will be noted here that for a better understanding, like components are designated by like reference numerals throughout the various figures.

The apparatus is configured to receive and retain the closure element such that the 30 closure element is disposed substantially within the apparatus. Thereby, if the apparatus is introduced via an introducer sheath, for example, the closure element can be disposed within, and delivered by way of, a lumen of the introducer sheath. The apparatus also is configured to engage the blood vessel wall adjacent to the opening and to position the

closure element substantially adjacent to an outer surface of the blood vessel wall adjacent to the opening.

When properly positioned, the apparatus can be activated to distally deploy the closure element. During deployment, the apparatus preferably is configured to substantially uniformly expand the closure element beyond a natural cross-section of the closure element such that the closure element, when deployed, is configured to engage significant amount of the blood vessel wall and/or tissue. Engaging the blood vessel wall and/or tissue, the closure element is further configured to return to the natural cross-section. Thereby, the engaged blood vessel wall and/or tissue are drawn substantially closed and/or sealed, such that, for example, hemostasis within the opening is enhanced.

In one specific embodiment, an apparatus is provided for delivering and deploying a substantially resilient closure element through tissue to an opening in a body lumen peripherally defined by opposing arterial walls. The closure element is configured to substantially uniformly deform from a natural, substantially resilient planar configuration to a substantially tubular configuration, having a substantially natural transverse cross-sectional dimension. The apparatus include a delivery assembly positionable through the tissue and into the opening in the body lumen, and having a distal tissue engaging device and a carrier assembly. The carrier assembly is configured to carry and support the closure element in the substantially tubular configuration in a first diameter. The distal tissue engaging device is selectively axially displaceable relative to at least a portion of the carrier assembly between a tissue engaging condition and a tissue closing condition. In the tissue engaging condition, the opposing arterial walls of the body lumen are engaged adjacent to the opening. In contrast, in the tissue closing condition, the engaged opposing arterial walls are urged substantially transversely together such that the closure element may be deployed from the delivery assembly, while substantially maintained in the first diameter, into the opposing arterial walls. The closure element is oriented to engage the engaged opposing arterial walls when deployed and to return to the natural, substantially planar configuration and the natural, transverse cross-sectional dimension such that the engaged opposing arterial walls are drawn substantially closed.

The distal tissue engaging device includes two or more opposed engaging tongs having respective end tips configured to open radially in directions extending beyond the first diameter of the carrier assembly to initially engage the opposing arterial walls, in the engaging condition. These engaging tongs are configured to close radially inward such

that the engaged opposing arterial walls are disposed within the first diameter of the closure element, in the substantially tubular configuration, in the closing condition.

In another specific embodiment, the carrier assembly includes a cover member protecting the delivery assembly such that at least the closure element is contained therein. The cover member defines a lumen configured for slidable receipt of the closure element therein. The distal tissue engaging device is integral with a distal end of the cover member to enable movement of the two or more opposing tongs between the engaging condition and the closing condition.

Still another specific arrangement provides a delivery assembly that is formed and dimensioned for sliding axial, reciprocating, receipt in a lumen of an introducer sheath extending through the tissue and terminating proximate the opening. The tissue engaging device is configured to cooperate with the introducer sheath to enable movement between the engaging condition and the closing condition. Further, the two or more tongs are formed and dimensioned for sliding contact with the sheath lumen to effect movement between the engaging condition and the closing condition.

In yet another specific embodiment, the carrier assembly includes a carrier seat configured to seat the closure element, in the substantially tubular configuration, on the delivery assembly prior to deployment. The delivery assembly includes a tubular body supporting the carrier seat, and defines a central receiving lumen extending longitudinally therethrough that is configured for sliding support of the tissue engaging device for axial movement between the engaging condition and the closing condition. Each of the two or more tongs are bowed and biased radially outward, relative one another, from a longitudinal axis of the tubular body such that an end tip of each respective tong is urged outward and toward gripping intravascular engagement with an undersurface of the opposing arterial walls, in the engaging condition, when the tissue engaging device extends distally from the central lumen of the tubular body.

In another aspect of the present invention, a closure system is provided for closing an opening formed in a body lumen peripherally defined by opposing arterial walls. The system includes a closure element adapted to deform from a natural, substantially resilient planar configuration to a substantially tubular configuration, having a substantially natural transverse cross-sectional dimension. A delivery assembly is positionable through the tissue and into the opening in the body lumen. The delivery assembly includes an elongated body, a carrier assembly and a distal tissue engaging device. The carrier assembly includes a carrier seat configured to carry and peripherally

support the closure element in the substantially tubular configuration, in a first diameter. The distal tissue engaging device is selectively axially displaceable relative to the carrier seat between the engaging condition and the closing condition, while substantially maintaining the engaged walls within the first diameter. A pusher member is slidably disposed about the elongated body for relative axial sliding displacement therebetween. The pusher member includes a contact portion disposed proximally adjacent the closure element. The pusher member is applied to selectively distally deploy the closure element from the carrier assembly, in the substantially tubular configuration, to engage the opposing arterial walls and to return to the natural, substantially planar configuration and the natural, transverse cross-sectional dimension such that the engaged opposing arterial walls are drawn substantially closed.

In yet another aspect of the present invention, a method for closing an opening perimetrically defined by edges of the arterial walls of a body lumen is provided including placing a distal end region of a locator portion of a through tissue into the opening; and engaging the arterial walls adjacent to the opening. The method further includes positioning a distal end region of a carrier assembly through the tissue adjacent to the opening. The carrier assembly is oriented proximal to the locator portion, and the distal end region of the carrier assembly includes a carrier seat configured to seat the closure element thereon in a substantially tubular configuration, having a first diameter. The method includes urging the engaged arterial walls radially inward and toward one another such that at least opposed edges of the arterial walls drawn with the first diameter of the closure element. The closure element is distally deployed from the carrier assembly without further substantial radial expansion for the closure element, in the substantially tubular configuration, such that the closure element engages the arterial walls, and returns to the natural, planar configuration and the natural cross-section wherein the tissue is drawn substantially closed.

In one specific embodiment, the engaging of the arterial walls is performed by extravascularly engaging the arterial walls with a tissue engaging device. In contrast, the engaging of the arterial walls is performed by intravascularly engaging the arterial walls with a tissue engaging device.

Referring now generally to FIGURES 1-4 and 8A-8H, a clip or closure applier apparatus, generally designated 100, is provided for delivering and deploying a closure element 500 to an opening 610 formed in a body lumen, such as a blood vessel 600; the opening 610 of which is perimetrically defined by opposing tissue arterial walls 620',

620" (FIGURE 8A). Briefly, as shown in FIGURES 3A-3G, the closure element 500 itself is configured to resiliently deform between a natural, substantially planar configuration (after a curing process (FIGURE 3C)) to a substantially tubular configuration (FIGURE 3F and 3G). Further, the closure element can also be resiliently deformed and radially displaced up to an expanded substantially tubular configuration, having a greater cross-sectional dimension, from its natural substantially tubular configuration (FIGURE 8F and 8G), or can be displaced down to a reduced substantially tubular configuration, having a lesser cross-sectional dimension.

Returning to the clip applier apparatus 100, in accordance with the present invention, a delivery assembly, generally designated 200, is included that is positionable through the tissue 630 and into the opening 610. The delivery assembly 200 includes a distal tissue engaging device 400 and a carrier assembly 300, oriented just proximal to the distal tissue engaging device, that houses and supports the closure element 500". The carrier assembly 300 includes a carrier seat portion 302 configured to carry and support the closure element 500" in a slightly expanded substantially tubular configuration (FIGURE 7A-7C), in a first diameter, that is slightly greater than that in a natural, substantially tubular condition.

The distal tissue engaging device 400 is selectively axially displaceable relative to the carrier assembly 300 between a tissue engaging condition (FIGURE 8D) and a tissue closing condition (FIGURE 8F). In the tissue engaging condition, the tissue engaging device 400 engages the opposing arterial walls 620', 620" (e.g., FIGURE 8D-8E) of the body vessel 600 adjacent to the opening 610 so that the engaged walls can be pulled or urged radially inward or transversely toward one another in the closing condition (FIGURE 8F-8G). Hence, in the closing condition, the engaging device 400 urges the opposing arterial walls 620', 620" at the opening 610, substantially closer together and toward one another radially. By closing the opposing arterial walls within the first diameter of the closure element 500" (mounted about the carrier seat 302 in the substantially tubular configuration), the closure element can be deployed directly therefrom without having to further radially expand the same to sufficiently engage the tissue.

Hence, applying a pusher member 320 (as will be described), the closure element 500", which is retained in the substantially tubular configuration, can be deployed into the opposing arterial walls (FIGURE 8G). Subsequently, once the closure element engages the opposing arterial walls 620', 620" and is released from the delivery assembly, it returns to the natural, substantially planar configuration and the natural cross-section

dimension such that the engaged opposing arterial walls are drawn substantially closed (FIGURE 8H).

In accordance with the present invention, since the closure element 500” can be deployed from the closure applier apparatus 100 without requiring substantial further 5 radial expansion from the substantially tubular configuration atop the carrier assembly, the overall complexity of the closure applier can be significantly reduced. In turn, the diametric footprint can be significantly reduced, as compared to previous designs, which in effect permit the use of a smaller diameter introducer sheath, e.g. 6F introducer sheath. Moreover, a closure applier apparatus is provided that fully encloses the closure element 10 within itself during advancement to the tissue site, prior to deployment and delivery to the targeted vessel walls. Unlike many current designs, the present invention significantly reduces potential tissue snag or contact by the closure element during advancement and positioning. This enclosure approach is similar to those disclosed in co-pending U.S. Patent App. S/N: 11/455,993, filed June 19, 2006, and entitled “APPARATUS AND 15 METHOD FOR DELIVERING A CLOSURE ELEMENT”; and U.S. Patent App. S/N: 10/356,214, filed January 30, 2003, entitled “CLIP APPLIER AND METHODS OF USE” (hereinafter referred to as the ‘214 Patent Application), each of which is herein incorporated by reference in their entirety. These designs prove much more desirable and provide a basis for a wide range of medical applications, such as diagnostic and/or 20 therapeutic procedures involving blood vessels or other body lumens of any size.

As will be discussed in more detail below, the clip applier apparatus 100 can deliver a closure element 500” (shown in FIGURES 3F-G) through tissue 630 (shown in FIGURE 8A) and into an opening 610 formed in and/or adjacent to and peripherally defined peripherally by the arterial walls 620 (e.g., the opposed arterial walls 620’, 25 620”) of a blood vessel 600 or other body lumen. The closure element (or clip) 500 preferably has a generally annular-shape body 510 (shown in FIGURES 3A-3B) defining a channel 540 and one or more barbs and/or tines 520 for receiving and engaging the blood vessel wall 620 and/or the tissue 630 around the opening 610. Although the closure element 500, when originally fabricated, has a natural shape and size, the closure element 30 500 can be deformed into other shapes and sizes, as desired, and is configured to return to the natural shape and size when released. For example, the closure element 500 can have a natural, planar configuration with opposing tines 520 and a natural cross-section 530 as shown in FIGURES 3A-3B. Via a heat-treating process, disclosed in U.S. Patent No. 6,623,510 to Carley et al., incorporated herein by reference in its entirety, the natural

cross-section 530 of the closure element 500 will be reduced to form a reduced closure element 500' that has a natural, planar configuration with opposing tines 520 and a reduced cross-section 530' as shown in FIGURES 3C-3D. By rotating the opposing tines 520 axially as shown in FIGURE 3E, the cured closure element 500' can be further 5 deformed to form a substantially tubular closure element 500" (shown in FIGURE 3F) having a generally annular-shape body 510' with an outer diameter 530' and an inner diameter 550. In this substantially tubular configuration with the tines 520 in an axial configuration (FIGURE 3G which is the configuration when loaded on the carrier assembly configuration, albeit slightly expanded), the resulting cross-section 530' when 10 loaded is expanded as well.

Being configured to draw the opposed blood vessel arterial walls 620', 620" and/or the tissue 630 adjacent to the opening 610 substantially closed and/or to enhance hemostasis within the opening 610, the closure element 500 can be formed from any suitable material, including any biodegradable material, any shape memory alloy, such as 15 alloys of nickel-titanium, or any combination thereof. As desired, the closure element 500 can include radiopaque markers (not shown) or can be wholly or partially formed from a radiopaque material to facilitate observation of the closure element 500 using fluoroscopy or other imaging systems. Exemplary embodiments of a closure element are disclosed in U.S. Pat. No. 6,197,042, in co-pending application Ser. Nos.: 09/546,998; 20 09/610,238 and 10/081,726. The disclosures of these references and any others cited therein are expressly incorporated herein by reference.

With the exception of the last specific embodiment shown in FIGURE 15, the clip applier apparatus 100 is configured to receive, retain and substantially enclose the closure element 500" within the apparatus 100. In the embodiments of FIGURES 1-2 and 4-15, 25 as will be described in greater detail below, the delivery assembly 200 includes an elongated tubular body 210 that supports a distal tissue locator portion 202 and the carrier seat 302 of the carrier assembly 300 that is disposed proximal to the locator portion. The carrier assembly 300 further includes a cylindrical cover member or garage tube 330 enclosing the pusher member 320, the tubular body 210 and the carrier seat 302 in a 30 nested manner within its receiving lumen 334 until the closure element is prepared for deployment.

In each embodiment, if the apparatus 100 is introduced via an introducer sheath 640 (shown in FIGURE 8A), for example, the closure element 500" can be disposed entirely within the garage tube 330, and delivered by way of the lumen 644 (shown in

FIGURE 8A) of the introducer sheath 640. Being disposed substantially within the garage tube 330 of the clip applier apparatus 100 just prior to deployment of the closure element 500", the delivery assembly 200 can deeply penetrate the tissue 630 adjacent to the opening 610 without inadvertently contacting or snaring it. The delivery assembly 5 200 can thus position the closure element 500" substantially adjacent to an outer surface 620a (shown in FIGURE 8A) of the blood vessel wall 620 adjacent to the opening 610.

Referring to the specific embodiments of FIGURES 1-2 and 4-15, each clip applier apparatus 100 includes a central distal tissue locator portion 202 and a carrier assembly 300 supported on the end of, and integrated with, the tubular body 210 of the 10 delivery assembly 200. Briefly, the distal locator portion 202 is configured to facilitate location of the opening 610 into the blood vessel 600, relative to the carrier assembly 300 and the tissue engaging device 400 (e.g., FIGURES 8D and 8E).

The carrier assembly 300, on the other hand, is configured to carry and support the closure element 500" in the substantially tubular configuration (FIGURES 3F and 3G), 15 albeit in a slightly expanded configuration from its natural tubular configuration. In this manner, the resiliency of the closure element 500" itself, together with the confinement of the cover member 330, function to secure it to the carrier seat 302 of the carrier assembly 300. When deployed, the closure element 500" (in the substantially tubular configuration) is oriented with its tines directed distally to engage the blood vessel wall 20 620 and/or the tissue 630 around the opening 610, and to return to the natural, substantially planar configuration and the natural cross-section such that the engaged tissue is drawn substantially closed (FIGURE 8H).

Once strategically oriented, the clip applier apparatus 100 can be activated to distally deploy the closure element 500". It will be appreciated that although the closure 25 element 500" is capable of significantly greater radial expansion from its tubular configuration mounted to the carrier assembly 300 of the tubular body 210, the delivery assembly is designed to deploy the closure element 500" directly from the carrier seat 302 without requiring any further significant radial expansion.

The apparatus 100 can be provided as one or more integrated components and/or 30 discrete components. As shown in the embodiment of FIGURES 1-2 and 4-8, for example, the apparatus 100 can include an elongated delivery assembly 200 having an integral tissue engaging device 400, central vessel locator (or obturator) portion 202 and carrier assembly 300, that carries the closure element 500" thereon, on a single subsystem. In contrast, in the embodiments of FIGURES 9-15, the tissue engaging

device 400 is contained on a separate subsystem from the carrier assembly 300 and the vessel locator portion 202, all of which cooperate with one another to deploy the closure element.

In fact, in accordance with the present invention, it is the position, implementation and execution of the tissue engaging device 400 that differentiates each embodiment. In one specific embodiment, for example, the tissue engaging device 400 is disposed on the distal end to the cover member 330 (FIGURES 1-2, and 4-8), where it is selectively operated between the tissue engaging condition (FIGURES 8D, 8E) and the closing condition (FIGURES 8F, 8G). In contrast, in the embodiments of FIGURES 9-15, the tissue engaging device 400 is disposed within a central lumen 204 of the tissue locator portion 202, and is selectively operated as it is distally advanced from the lumen. It will be appreciated that these differing implementations of the tissue engaging devices will each be detailed separately below.

In each implementations, however, the tissue engaging device 400 is capable of gripping, snaring and/or piercing the tissue arterial walls 620, and urging them together and radially inward, toward one another, such that portions of the arterial walls 620', 620'' are axially contained within the first diameter of the closure element 500'', in the substantially tubular configuration. As mentioned, this arrangement enables the deployment of the closure element 500'' directly from the carrier seat 302 of the carrier assembly 300 without requiring further radial expansion.

Referring back to FIGURES 4-8, the first specific embodiment will be described in detail. In this particular arrangement, the distal tissue locator portion 202 (obturator) is configured to extend into the opening 610 and selectively engage an inner surface 620b of the blood vessel wall 620 (FIGURE 8D). Thereby, the distal locator portion 202 is configured to draw the blood vessel wall 620 taut, and maintain the proper position of the clip applier apparatus 100 as the blood vessel 600 pulsates. Briefly, in cooperation with the tissue engaging device 400 oriented at the distal end of the cover member 330, once the distal locator portion 202 is properly aligned and positioned, the tissue engaging device can be operated to engage the arterial walls, drawing them radially together as will be described below.

First, the delivery assembly 200 of this embodiment will be detailed which includes the tubular body 210, the carrier assembly 300 and the distal locator portion 202 integrated on a single subsystem. The tubular body 210 is preferably provided by a flexible, semi-rigid or rigid, tubular structure, such as an elongate rail, with a longitudinal

axis 216. As illustrated in FIGURES 2 and 4A, the tubular body 210 has a proximal end region 210a and a distal end region 210b that supports the carrier seat 302 of the carrier assembly 300 just proximal to the distal locator portion 202.

The tubular body 210 is preferably of a predetermined length 218a and a predetermined outer cross-section 218b (FIGURE 2), both of which can be of any suitable dimension. The distal section of the distal locator portion 202 preferably includes a substantially rounded, soft, and/or flexible distal end or tip 220 to facilitate atraumatic advancement and/or retraction of the distal section into the blood vessel 600. As desired, a pigtail (not shown) may be provided on the distal end 220 to further aid atraumatic advancement of the delivery assembly 200.

Turning now to FIGURES 4A and 4B, it will be appreciated that the distal locator portion 202 functions in a manner similar to those disclosed in co-pending application Ser. Nos. 09/732,835 and 10/081,723, the disclosure of which is expressly incorporated herein by reference. That is, the distal locator portion 202 is selectively controllable between an unexpanded state (FIGURE 4A) and an expanded state (FIGURE 4B). In the unexpanded state, the distal locator portion 202 has an unexpanded size; whereas, in the expanded state, it has an expanded size, which is greater than the unexpanded size in the unexpanded state. The distal locator portion 202 is configured to expand from the unexpanded size to the expanded size and/or to contract from the expanded size to the unexpanded size, and the expansion and contraction of the distal locator portion 202 preferably is substantially uniform about the longitudinal axis 216. For example, one or more expansion elements 230 can be provided on the distal locator portion 202 and can be configured to expand substantially transversely with respect to a longitudinal axis 216 of the locator portion 202. Preferably being substantially equally distributed about an outer periphery 212 of the distal locator portion 202, the expansion elements 230 may include radiopaque markers (not shown) or may be wholly or partially formed from a radiopaque material to facilitate observation of the expansion elements 230 and/or the distal locator portion 202 using fluoroscopy or other imaging systems.

At least one, and preferably all, of the expansion elements 230 of the distal locator portion 202 can comprise a substantially flexible member 230' with a substantially fixed end region 230a', an intermediate region 230b', and a movable end region 230c' as shown in FIGURES 4A-4B. For each substantially flexible member 230', the proximal fixed end region 230a' is fixedly coupled, relatively, with an intermediary support region 211 separating the distal locator portion 202 from the carrier assembly 300. In contrast, the

movable end region 230c' is movably coupled, relatively, with the intermediary support region 211, and configured to be axially movable relative to the fixed end region 230a'. When each movable end region 230c' is axially moved toward the relevant fixed end region 230a', the intermediate regions 230b' buckle and/or expand transversely outwardly, 5 thereby transitioning the distal locator portion 202 of the delivery assembly 200 from the unexpanded state to the expanded state. In contrast, the distal locator portion 202 transitions from the expanded state to the unexpanded state as each of the movable end regions 230c' are axially moved away from the relevant fixed end region 230a'.

Hence, the expansion elements 230 are relatively resilient, and can buckle without 10 plastic deformation or pure elastic deformation. Further, although the expansion elements 230 are shown as comprising the flexible members 230' in FIGURES 4A-4B for purposes of illustration, it is understood that the expansion elements 230 can comprise any type of expansion elements and are not limited to the illustrated embodiments. For example, inflatable bladder type devices or the like may be employed to cause expansion of the 15 expansion elements, such as a balloon, an expandable mesh or a slit hypotube, etc. In a preferred embodiment, the flexible members are constructed of nitinol.

Referring back to FIGURES 1 and 4-6, the delivery assembly 200 also includes the carrier assembly 300 positioned along the distal end of the tubular body 210, and oriented adjacent and proximate to the distal locator portion 202. The carrier assembly 20 300 is configured to receive and retain the closure element 500" in the slightly expanded, substantially tubular configuration (shown in FIGURE 7B), which preferably is disposed substantially within the cover member 330 of the carrier assembly 300. The carrier assembly 300 includes a substantially cylindrical-shaped carrier seat 302 configured to seat the closure element 500" thereagainst. By parking the closure element 500" within 25 the garage tube 330 (or cover member) during vessel advancement or positioning, not only is any tissue snaring caused by the closure element reduced, but the closure element itself is protected within the confines of the cover member.

Turning now to FIGURES 5A-5C, the carrier assembly 300 preferably includes the carrier seat 302, the pusher member 320, and the cover member (garage tube) 330. 30 These components are preferably provided as a plurality of nested, telescoping members with a common longitudinal axis 350. As mentioned, the substantially cylindrical-shaped seat surface or the carrier seat 302 is sized and dimensioned to have transverse cross-sectional dimension slightly greater than that of the closure element 500", when the closure element is deformed to its natural substantially tubular configuration. Thus, the

closure element 500 preferably is deformed from its natural, planar configuration (FIGURES 3A, 3B) to the natural, substantially tubular closure element 500" (shown in FIGURES 3F, 3G). When being placed or positioned about an outer periphery of the carrier seat 302, the closure element must further be slightly radially expanded to fit 5 thereover. In this arrangement, the tines 520 of the substantially tubular closure element 500" are pointed substantially distally and ready for tissue engagement. Once seated, the closure element 500" will primarily be retained in place using its own resiliency toward the natural planar position from the slightly expanded, substantially tubular configuration about the seat surface.

10 A biocompatible glue or adhesive may further be applied to facilitate retaining the closure element 500" on the carrier seat 302 of the carrier assembly 300. Together with the internal restrictive or confining nature of the cover member 330, the glue or adhesive must be sufficient to overcome the resilient tendency of the closure element 500" (FIGURE 3G) to return to its natural planar condition (FIGURES 3A and 3B). By way of 15 example, such glues and embedded adhesives include polymer coatings, Loctite, etc. It will further be appreciated that other techniques can be applied to retain the closure element 500" to the carrier seat 302.

In accordance with the present invention, the pusher member 320 is configured to 20 slidably receive at least a portion of the carrier seat 302, as well as the tubular body 210, with a receiving lumen 324 therein and an external surface 322b. The pusher member 320 is of a predetermined length 328a and a predetermined cross-section 328b, both of which can be of any suitable dimension. The predetermined length 328a of the pusher member 320 can be greater than or substantially equal to the collective predetermined length 218a and diameter 218b of the tubular body 210 and the carrier assembly 300. The 25 predetermined length 328a of the pusher member 320, however, is preferably less than the collective predetermined length 218a of the tubular body 210 and the carrier seat 302, such that a distal end region 320b of the pusher member 320 is axially offset proximally from the distal end region 302b of the carrier seat 302. This axial offset, together with the cover member 330, defines an annular space 360 designated for receipt of the 30 substantially tubular closure element 500" about the carrier seat 302.

Being formed from a substantially rigid, semi-rigid, or flexible material, the pusher member 320 preferably is substantially tubular and defines receiving lumen 324 that extends substantially between the proximal end region 320a and the distal end region 320b. This lumen 324 is configured to slidably receive at least a portion of the tubular

body 210 and the carrier seat 302 therethrough. The cross-section 328b of the pusher member 320 preferably is substantially uniform, and the distal end region 320b of the pusher member 320 can comprise one or more longitudinal extensions 325, which extend distally from the pusher member 320 and along the periphery of the carrier seat 302, as shown in FIGURE 5B. The longitudinal extensions 325 preferably are biased such that the longitudinal extensions 325 extend generally in parallel with common longitudinal axis 350. The longitudinal extensions 325 are sufficiently flexible to expand radially, and yet sufficiently rigid to inhibit buckling.

As best shown in FIGURES 5A and 5C, the cover member 330 is configured to retain the substantially tubular closure element 500" and the carrier assembly 300 substantially within a lumen 334 thereof prior to deployment. Being coupled with, and slideable relative to, the carrier seat 302 and the pusher member 320, the cover member 330 has a proximal end region 330a and a distal end region 330b and includes a predetermined length 338a and a predetermined cross-section 338b. Preferably being formed as a substantially rigid, semi-rigid, or flexible tubular member formed from a polymer, the cover member 330 has an outer periphery 332b and an inner periphery 332a that defines lumen 334. The lumen 334 extends substantially between the proximal and distal end regions 330a, 330b of the cover member 330 and can be configured to slidably receive at least a portion of the pusher member 320. When the cover member 330 is properly positioned over the pusher member 320 and the carrier seat 302, the distal end region 330b is configured to extend over the space 360, thereby defining an annular cavity for receiving and retaining the closure element 500" in the substantially tubular configuration.

In one preferred embodiment, as best illustrated in FIGURE 5A, 5C, 7B and 7C, one or more longitudinal extensions 335 extend distally from the garage tube or cover member 330. Although the longitudinal extensions 335 can extend generally in parallel with common longitudinal axis 350, the longitudinal extensions 335 preferably are biased such that the plurality of longitudinal extensions 335 extend substantially radially inwardly as illustrated in FIGURES 5A and 5C. Thereby, the longitudinal extensions 335 can at least partially close the annular space 360 slotted for seating of the closure element 500".

The cross-section 338b of the cover member 330 preferably is substantially uniform. In the embodiment of FIGURES 1, 2 and 4-8, the distal end region 330b of the cover member 330 is integrated with the tissue engaging device 400, as will soon be

detailed. To permit the substantially tubular closure element 500" to be deployed from the annular space 360, the cover member 330 can be slidably retracted, relative the carrier seat 302 to expose the mounted closure element 500".

If the carrier assembly 300 is assembled as a plurality of nested, telescoping members as shown in FIGURE 5A, the tubular body 210 of the delivery assembly is at least partially disposed within, and slideable relative to, the lumen 324 of the pusher member 320. The pusher member 320, in turn, is at least partially disposed within, and slideable relative to, the lumen 334 of the cover member 330. Hence, the longitudinal axis 216 of the locator portion 202, the carrier assembly 300 and the tubular body 210 (i.e., of the delivery assembly 200) are preferably substantially in axial alignment with the common longitudinal axis 350 of the pusher member 320 and the cover member 330.

In accordance with this embodiment of the present invention, the tissue engaging device 400 is disposed and oriented on the distal end of the cover member 330 for operation between the tissue engaging condition (FIGURE 8D, 8E) and the tissue closing condition (FIGURE 8F, 8G). As previously indicated, in the tissue engaging condition, the tissue engaging device 400 engages the opposing arterial walls 620', 620" (e.g., FIGURE 8E) of the vessel 600 adjacent to the opening 610 so that they can be pulled or urged radially inward or transversely toward one another in the closing condition (FIGURE 8F). In the closing condition, hence, the engaging device 400 urges the opposing arterial walls 620', 620" at the vessel opening 610, substantially radially together about axis 216 and toward one another. By closing the opposing arterial walls within the first diameter of the closure element 500", the closure element can be deployed directly from the carrier seat 302 of the carrier assembly 300 without having to further radially expand to sufficiently engage the tissue.

As best illustrated in FIGURE 7B, the engaging device 400 includes at least two opposing tongs 402, each of which extends distally from the distal end of the cover member and terminates at a tissue engaging tip 404. The tips 404 may be conventionally pointed shaped that facilitate penetration and/or snaring of tissue during operation. These tongs, preferably integral with the cover member or garage tube 330, are sufficiently flexible to enable control and operation in and by the introducer sheath 640, yet are sufficiently rigid to enable extravascular penetration, snaring and/or grasping of the target arterial wall. In one specific configuration, for example, the distal end of the garage tube may be fabricated from a material having shape memory properties where, in use, the

combined subsystem would cooperate the introducer sheath 640 to operate and control the use of the tissue engaging device 400.

The two or more tongs 402 of the tissue engaging device 400 are configured and oriented for sliding reciprocal cooperation with an interior wall 642 of the sheath 640 to control movement and operation of the engaging device between the tissue engaging condition (FIGURES 8D, 8E) and the closing condition (FIGURES 8F, 8G). More specifically, the distal tips 404 of each tong 402, in the tissue engaging condition, will be manipulated to snare and/or engage the arterial walls 620', 620" being held taut by the tissue locator portion 202, in the expanded condition. Preferably, the engaging device 10 distal tips 404 will be radially expanded or oriented at least as wide as the first diameter, relative to longitudinal axes 216, 350, of the closure element seated about the carrier seat 302. More preferably, the distal tips 404 will be radially expanded to a disposition greater than and beyond the first diameter to ensure sufficient snaring and/or engaging of the arterial walls surrounding the vessel opening 610. Accordingly, the tongs of the tissue 15 engaging device are biased and/or have a disposition extending radially outward. Hence, by retracting the restrictive sheath 640 proximally relative to the garage tube 330 (or advancing the delivery assembly distally past the distal end of the sheath), the respective tongs 402 of the tissue engaging device 400 will be released and permitted to radially expand to the tissue engaging position (FIGURE 8D).

20 Briefly, as will be described in greater detail below, once the arterial walls 620', 620" are snared or pierced by the tissue engaging device 400, in the tissue engaging condition, the introducer sheath can be displaced distally, relative to the garage tube. Sliding contact between the interior wall 642 of the sheath and the outer facing surfaces 25 406 of the tongs 402 causes the distal tips of the engaging device to draw the tissue radially inward toward one another (FIGURE 8F). As the interior wall 642 of the sheath is advanced distally, the increasing contact along the outer surfaces 406 of the tongs causes the distal tips to invert inwardly within the first diameter of the closure element in the substantially tubular configuration about the carrier seat 302, in the closing condition.

30 FIGURE 6 best illustrates that the clip applier apparatus 100 includes a housing/handle 380 at a proximal end thereof suitable for gripping and manual support, manipulation and operation of the device and components thereof. Preferably, the housing 380 is an elongated member having a proximal end 380a and a distal end 380b with a longitudinal axis 386. When the apparatus 100 is properly assembled, the tube set 305 of the delivery assembly 200 is at least partially disposed within the housing handle

such that the pusher member 320 and the cover member 330 are slidable relative to the housing 380, the tubular body 210, the carrier seat 302 and the distal locator portion 202 thereof. Further, respective distal end regions 210b, 320b and 330b extend from the distal end region 380b of the housing 380 such that the common longitudinal axis 350 (shown in FIGURE 5A) of the tube set 305 is substantially axially aligned with the longitudinal axis 386 of the housing 380. Being configured to slidably retain the respective proximal end regions 210a, 320a and 330a, the housing 380 supports the tube set 305 and can have one or more handles 390 to facilitate use of the apparatus 100. The handles 390 extend substantially radially from the outer periphery 382 of the housing 380 and can be provided in the manner known in the art.

The present invention incorporates various switching systems, triggering systems, locking systems, etc. contained in the handle portion to effect use and operation of the delivery components described herein. While all these subsystems are not shown and described herein in detail, it will be appreciated that they are similar to the design and operation of the analogous subsystems shown and described in our '214 Patent Application, which as mentioned is incorporated by reference herein for all purposes.

By way of example, however, the locator portion 202 also can include a locator control system 240 that is coupled with the proximal end region 210a of the delivery assembly 200 and that is configured to selectively control the distal locator portion 202 between the unexpanded and expanded states (FIGURE 4C). The locator control system 240 can selectively control the distal locator portion 202 between the unexpanded and expanded states, such as by being activated by a switching system (not shown). For example, a control member 250, such as a rod, wire, or other elongate member, can be moveably disposed within a lumen (not shown) formed by the tubular body 210 and extending substantially between the proximal end region 210a of the tubular body 210 and the distal locator portion 202. The control member 250 has a proximal end region 250a that is coupled with the locator control system 240, preferably through a control block (not shown, but operationally similar to the control systems and structures), and a distal end section (not shown) of the control member 250 that is coupled with the expansion elements 230, and/or the movable end regions 230c' of the substantially flexible members 230'. The locator control system 240 can selectively transition the expansion elements 230, and/or the substantially flexible members 230' of the distal locator portion 202 between the unexpanded and expanded states by moving the control member 250 axially relative to the tubular body 210.

The locator control system 240 preferably includes a locator release system (not shown, but one embodiment which may be similar to that disclosed in the '214 patent application) for maintaining the unexpanded state and/or the expanded state of the distal end region 210b, the expansion elements 230, and/or the substantially flexible members 230'. The locator release system is preferably configured to maintain the locator portion in the expanded state. Any type of locking system can be employed, and can be engaged, for instance, by activating the switching system. For example, once the substantially flexible members 230' have entered the expanded state, the locator release system can secure the control member 250 to prevent axial movement relative to the tubular body 210, thereby maintaining the substantially flexible members 230' in the expanded state.

The locator control system 240 also can be configured to disengage the locator release system, such that the distal end region 210b, the expansion elements 230, and/or the substantially flexible members 230' can transition between the unexpanded and expanded states. The locator release system can be disengaged, for example, by activating an emergency release system (not shown). As desired, the locator control system 240 can further include a biasing system (not shown), such as one or more springs, to bias the distal end region 210b, the expansion elements 230, and/or the substantially flexible members 230' to enter and/or maintain the unexpanded state when the locator release system is disengaged.

In use, the closure element 500" is carried on the carrier seat 302, in the slightly radially expanded tubular configuration, and is disposed within the cover member 330. As shown in FIGURES 7A-7C, for example, the closure element 500' can be slidably received over the distal locator portion 202 and the distal end region of the carrier assembly 300. The closure element 500" is then seated and disposed about the periphery of the carrier seat 302 adjacent to the space 360, in the slightly expanded, substantially tubular configuration.

After being received over the distal end region 302b, the substantially tubular closure element 500" is disposed in the space 360, and the tines 520 are directed substantially distally as shown in FIGURE 7B. To improve the engagement between the closure element 500" (shown in FIGURES 3A-3B) and the blood vessel wall 620 and/or tissue 630 (collectively shown in FIGURE 8A), the substantially tubular closure element 500" preferably is disposed on the carrier seat 302 such that the tines 520 are contained in a plane.

Once disposed in the space 360, the resiliency of the slightly expanded closure element 500" and/or the addition of an adhesive or glue will facilitate retention of the element in place about the carrier seat. Moreover, the sliding receipt of the substantially tubular closure element 500" and the distal end region 320b of the pusher member 320 within the lumen 334 of the cover member 330, as illustrated in FIGURES 7B and 7C, also cooperate to retain the closure element 500" against the carrier seat 302. When the cover member 330 is properly positioned over the carrier assembly 300, the distal end region 330b (opposite of the proximal end region 330a) of the cover member 330 extends over the space 360 and defines the annular cavity for retaining the substantially tubular closure element 500". As such, the closure element 500" is disposed substantially between the outer periphery of the carrier seat 302 and the inner periphery 332a of the cover member 330 such that the substantially tubular closure element 500" maintains the substantially tubular configuration with the tines 520 being directed substantially distally. As desired, the tube set 305 may slightly radially compress the substantially tubular closure element 500" to facilitate seating against the carrier seat. The body 510 of the substantially tubular closure element 500" can be disposed distally of the distal end region 320b of the pusher member 320, as illustrated in FIGURES 7C, or can engage the distal end region 320b, as desired.

Turning now to FIGURES 8A-8H, operation of this specific embodiment will now be detailed. Initially, introducer sheath 640 may be inserted or otherwise positioned through skin 650 and tissue 630 and within the blood vessel 600 or other body lumen via the opening 610. Comprising a substantially flexible or semi-rigid tubular member, the sheath 640 has a proximal end region 640a and a distal end region 640b and includes a predetermined length and a predetermined cross-section, both of which can be of any suitable dimension. The sheath 640 also forms a peripheral surface 645 and a lumen 644 that extends along a longitudinal axis of the sheath 640 and substantially between the proximal and distal end regions 640a, 640b. The lumen 644 can have any suitable internal cross-section 648b and is suitable for receiving one or more devices (not shown), such as a catheter, a guide wire, or the like. The lumen 644 is configured to slidably receive tube set 305 and the delivery assembly 200 of the apparatus 100, including the nested tubular body 210, the carrier seat 302, the distal locator portion 202, pusher member 320 and the cover member 330 as a single unit. Accordingly, one significant advantage of the present invention is that, due to the reduced complexity of the cooperating componentry, the overall diametric footprint can be significantly smaller

relative to the current systems. Hence, the entire nested tube set 305 may be slidably received in the lumen 644 of the introducer sheath 640 without requiring a radial expansion or splitting of the sheath 640. Such a configuration is beneficial in that, when required, the delivery assembly 200 can be retracted and reinserted unlike the previous designs that irreversibly radially expanded, stretched, split or severed the analogous sheaths.

The introducer sheath 640 may be advanced over a guide wire or other rail (not shown) that was previously positioned through the opening 610 and into the blood vessel 600 using conventional procedures. In one specific use, the blood vessel 600 is a peripheral blood vessel, such as a femoral or carotid artery, although other body lumens may be accessed using the sheath 640 as will be appreciated by those skilled in the art. The opening 610, and consequently the sheath 640, may be oriented with respect to the blood vessel 600 such as to facilitate the introduction of devices through the lumen 644 of the sheath 640 and into the blood vessel 600 with minimal risk of damage to the blood vessel 600. One or more devices (not shown), such as a catheter, a guide wire, or the like, may be inserted through the sheath 640 and advanced to a predetermined location within the patient's body. For example, the devices may be used to perform a therapeutic or diagnostic procedure, such as angioplasty, atherectomy, stent implantation, and the like, within the patient's vasculature.

After the procedure is completed, the devices are removed from the sheath 640, and the apparatus 100 is prepared to be slidably received by the lumen 644 of the sheath 640 as shown in FIGURE 8B. Being in the unexpanded state, the distal end region of the distal locator portion 202, via tubular body 210, is slidably received by the lumen 644 and atraumatically advanced distally into the blood vessel 600 (FIGURE 8B). Briefly, it will be appreciated that, due to the fixed configuration between the distal end region of the carrier assembly 300 and the proximal end region of the distal locator portion 202, in a support configuration, that the carrier seat 302, the pusher member 320 and the cover member 330, together with the closure element in the slightly expanded, substantially tubular configuration, are also advanced distally near the blood vessel 600 as a unit. Moreover, since the pusher member 320 and the cover member 330 are also coupled to the tubular body 210, those components are likewise advanced distally together with the locator portion 202. Once the distal end region of the distal locator portion 202 extends into the blood vessel 600, the distal locator portion 202 can transition from the

unexpanded state (FIGURE 8B) to the expanded state (FIGURE 8C) by activating the switching system of the locator portion 202.

Turning now to FIGURE 8D, the apparatus 100 and the sheath 640 then are retracted proximally until the distal end region of the locator portion 202 is substantially adjacent to an inner surface 620b of the blood vessel wall 620. The distal end region of the locator portion 202 thereby draws the opposing blood vessel walls 620', 620'' taut and maintains the proper position of the apparatus 100 as the blood vessel 600 pulsates. Since the expanded cross-section of the expansion elements 230 is collectively greater than or substantially equal to the cross-section of the opening 610 and/or the cross-section of the lumen 644, the expansion elements remain in the blood vessel 600 and engage the inner surface 620b of the blood vessel wall 620. The expansion elements 230 can frictionally engage the inner surface 620b of the blood vessel wall 620, thereby securing the apparatus 100 to the blood vessel 600. The sheath 640 is then retracted proximally such that the distal end region 640b of the sheath 640 is substantially withdrawn from the blood vessel 600, as shown in FIGURE 8D, permitting the apparatus 100 to access the blood vessel wall 620.

While the relative distance between the distal end region of the carrier assembly 300 (i.e., the carrier seat 302) and the proximal end region of the distal locator portion 202 is preferably substantially fixed, it will be appreciated that such relative distances can be non-fixed as well. More particularly, upon establishing a first position of FIGURE 8D, the carrier seat 302 and the loaded closure element 500'', in the substantially tubular configuration, are disposed proximal and substantially adjacent to the outer surface 620a of the blood vessel wall 620. In this manner, the blood vessel wall 620, adjacent to the opening 610, is disposed substantially between the expanded distal region of the locator portion 202 and the distal end region of the carrier assembly 300.

Hence, once the distal end region of the locator portion 202 properly engages the inner surface 620b of the blood vessel wall 620 as the expansion elements 230 are selectively positioned and moved to the expanded state, the sheath 640 is further retracted proximally, exposing the tongs 402 of the tissue engaging device 400. As mentioned, the interior walls 642 of the sheath 640 cooperate with the garage tube 330 to maintain a substantially cylindrical profile, and to control and operate the use tongs 402 of the distal tissue engaging device, which are substantially distally facing and flush against the tubular body 210 when contained in the sheath 640. Further proximal retraction of the sheath 640 exposes the tongs 402 of the tissue engaging device 400 from inside the sheath

lumen 644, allowing the distal tips 404 of the tongs to radially expand toward the engaging condition.

Depending upon the particular design of the tissue engaging device 400, movement of the distal tips 404 of the tongs may occur in different ways. For instance, if 5 the tissue engaging device 400 is composed of a shape memory material, exposure of the heat set tissue engaging device 400 to the tissue environment causes radial expansion of the tongs 402 toward the engaging condition. In contrast, in a resilient, elbowed-type configuration of the engaging device tongs 402, as shown in FIGURE 8B-8E, proximal retraction of the reduces the compressive contact of the exterior facing surfaces of the 10 engaging device tongs 402 with the interior wall 642 of the sheath 640. This allows the distal tips 404 of the tongs to radially expand toward the engaging condition.

Once the tissue engaging device 400 has radially expanded to the tissue engaging condition, the garage tube 330 can be axially advanced distally, relative to the carrier assembly 300 and the tissue locator portion 202, maintaining the closure element 500" seated in the carrier seat 302 (not shown). It will be appreciated, however, that the tube set 305, with the exception of the tubular body 210, can be axially advanced along the tubular body together as a unit, as best viewed in FIGURE 8E. Hence, as the cover member is advanced distally, so is the pusher member 320 that unseats the closure element 500" from the carrier seat 302 about the tubular body 210. Consequently, the 15 distal tips 404 of the tongs, oriented distally toward arterial walls 620', 620" that define the vessel opening 610, are extravascularly advanced into piercing or snaring contact therewith. In cooperation with the expansion elements 230 of the distal locator portion 202, in the expanded condition, the arterial walls are maintained taut to facilitate engagement by the tongs.

25 Referring now to FIGURE 8F, the tissue engaging device 400 at the distal end of the garage tube 330 is collapsed together in the closing condition. This is performed by sliding the sheath 640 distally, relative to the carrier assembly 300 and the tissue locator portion 202 (or retracting the garage tube 330 into the sheath 640), increasing contact and engagement of the tongs 402 with the lumen interior wall 642 of the sheath. In effect, the 30 sliding contact pinches the distal tips 404 of the tissue engaging device tongs 402 together, pulling the opposed arterial walls 620', 620" radially inward toward the closing condition (i.e., within the first diameter of the closure element).

During operation of the tissue engaging device from the tissue engaging condition to the closing condition, the substantially tubular closure element 500" is advantageously

retained on the outer periphery of the carrier seat 302 by the cover member 330 as illustrated in FIGURE 8E. By retaining at least the proximal portion of the substantially tubular closure element 500” between the distal end region (e.g., the radially, inwardly directed longitudinal extensions 335) of the cover member 330 and the distal end region 5 of the carrier seat 302, the apparatus 100 is configured to provide better tissue penetration for the seated closure element 500”.

As mentioned, in one specific embodiment, the carrier seat 302 and the cover member 330 of the carrier assembly 300 cooperate to maintain the substantially tubular closure element 500” in the tubular configuration, and fixed relative to the distal tissue 10 engaging device 400. After the tissue engaging device 400 engages the opposed arterial walls 620’, 620” in the closing condition (FIGURE 8F), the locator release system (not shown) can be activated to transition the expansion elements 230 of the tissue locator portion or obturator 202 from the expanded state to the unexpanded state, as shown in FIGURE 8G.

15       The proximal end region of the locator portion 202 can be retracted proximally, effectively retracting the tubular body 210 and the distal locator portion 202 into the lumen 324 of the pusher member 320, and relative to the garage tube 330, closure element 500” and sheath 640 (FIGURE 8G). Simultaneously, the distal end of the pusher member 320 can be advanced distally, contacting the closure element 500” and advancing 20 it distally and axially along the tubular body 210 of the delivery assembly 100 and toward the tissue locator portion 202. Once the distal end region of the tissue locator portion 202 is axially proximate to the closure element 500” (e.g., seated about the expansion elements 230 of the tissue locator portion), the closure element is nearly ready to be deployed. The tissue locator portion 202 and the cover member 330 preferably are 25 inhibited from further relative axial movement and remain substantially stationary, relative the handle portion; whereas, the pusher member 320 remains axially slid able. As the pusher member 320 selectively continues distally, the distal end region 320b of the pusher member 320 further engages the substantially tubular closure element 500” and displaces it from its seating about the expansion elements 230 of the obturator (FIGURE 30 8G).

In accordance with the present invention, the closure element 500”, seated about the delivery assembly 200 in the slightly expanded, substantially tubular condition, is delivered into engagement with the opposed blood vessel arterial wall 620’, 620” and/or tissue 630 adjacent to the opening 610 without further radial expansion thereof. As

previously indicated, this benefit is due to the fact that the tissue engaging device 400 is simultaneously engaged with the vessel wall 620, and draws the opposed engaged sides walls 620', 620'' radially inward relative to one another and within the first diameter of the closure element.

Upon being advanced over the distal locator portion 202, in the unexpanded state, by the pusher member 320, the substantially tubular closure element 500'' is distally deployed as illustrated in FIGURE 8G. Continued distal advancement of the pusher member 320 past the distal end of the obturator delivers the tongs 402 of the closure element 500'' into piercing engagement with the arterial walls 620', 620'' surrounding the vessel opening. When the substantially tubular closure element 500'' is deployed, the tines 520 can pierce and otherwise engage significant amount of the blood vessel wall 620 and/or tissue 630 adjacent to the opening 610 without requiring significant further radio expansion in order to sufficiently engage the walls. Due to the simultaneous engagement of the tissue engaging device 400 with the vessel walls, the tines 520 can engage significant amount of the opposed blood vessel arterial walls 620', 620'' and/or tissue 630 because the vessel walls 620', 620'' are pulled together by the engaging device, in the closing condition. In particular, the tongs 402 of the tissue engaging device 400 engage the opposed vessel walls 620', 620'', and urge them radially inwardly, within the first diameter (and hence within the cross-section 530) of the substantially tubular closure element 500'' simultaneously while the pusher member 320 is deploying the closure element.

Once the substantially tubular closure element 500'' is deployed (FIGURE 8H), it begins to transition from the tubular configuration to the natural, planar configuration with opposing tines 520 and a natural cross-section 530 of the closure element 500''. Preferably, the substantially tubular closure element 500'' substantially uniformly transitions from the tubular configuration to the natural, planar configuration. Rotating axially inwardly to form the opposing tines 520 of the closure element 500'', the tines 520 draw the tissue 630 and/or opposing vessel walls 620', 620'' into the channel 540 of the transitioning closure element 500''. In addition, the tissue 630 is drawn substantially closed and/or sealed as the cross-section 530' of the substantially tubular closure element 500'' contracts to return to the natural cross-section 530 of the closure element 500. Thereby, the opening 610 in the blood vessel wall 620 can be drawn substantially closed and/or sealed via the closure element 500 as illustrated in FIGURE 8H. Subsequently, the

sheath 640 and the tube set 305 of the delivery assembly 200 can be withdrawn from the tissue 630.

To reduce interference of the closure element tines 520 with the tissue engaging tongs, while the tongs are engaged with the vessel walls 620', 620" in the closing condition, the tips 404 and the tongs 402 can be configured so as to be angularly off-set (at virtually any angle resulting in non-interference) from one another (not shown) about the common longitudinal axis 350. For example, as little as about a 5 degrees angular off-set between the engaging device tongs 402 and the closure element tines 520, about the common longitudinal axis 350, will significantly reduce contact of the tines with the tongs during delivery of the closure element.

Turning now to FIGURES 9 and 10, an alternative embodiment delivery assembly 200 is illustrated wherein the tissue engaging device 400 is disposed within and deployed from a central lumen 204 of the tubular body 210. As indicated above, the primary difference between the various embodiments of the present invention is the location, implementation and execution of the tissue engaging device 400. For example, in this embodiment, the tissue engaging device 400 is configured to intravascularly engage the opposing arterial walls 620', 620", while in the previous embodiment, the tissue engaging device extravascularly engages the arterial walls.

The primary orientation and operation of the remaining components of the delivery assembly 200, however, are similar to the previously discussed embodiments. That is, the delivery assembly 200 contains a similar tube set 305 consisting of the locator portion 202 and the carrier assembly 300, the carrier assembly of which is located at the distal end of the tubular body 210, just proximal to the locator portion 202. Briefly, the carrier assembly 300 similarly consists of the carrier seat 302, the tubular pusher member 320 and a nested garage tube 330; the latter of which surrounds the former two, and all of which are coaxial with longitudinal axis 216 of the tubular body 210.

The tissue locator portion 202 includes a tubular bleed back shaft 260 distally extending from a distal end of the carrier seat 302. Preferably, both the carrier seat and the bleed back shaft 260 are integrally formed with one another on the end of the delivery assembly tubular body 210. The bleed back shaft 260 includes a bleed back port 262 that functions to locate the vessel opening 610 at puncture site in the vessel 600. This port 262 is oriented a predetermined distance from the distal end from the bleed back shaft 260. The bleed back port 262 communicates with a bleed back lumen (not shown) that longitudinally extends from the locator portion and through the tubular body 210 of the

delivery assembly, although it will be appreciated that the port could also share a lumen with the tissue engaging device.

In accordance with this specific embodiment, the cover member or garage tube 330 similarly covers the pusher member 320, the carrier seat 302 of the carrier assembly 300, and the tubular body 210 (i.e., tube set 305). Since the tissue engaging device is not disposed at the distal end of the garage tube, the annular distal end preferably terminates just distal to the carrier seat 302, defining the annular space 360 that seats the closure element 500" in the substantially tubular configuration. In one preferred embodiment, one or more longitudinal extensions extend distally from the garage tube or cover member 330, similar to extensions 355 of FIGURE 7B. Although these longitudinal extensions can extend generally in parallel with common longitudinal axis 350, the longitudinal extensions preferably are biased such that they extend substantially radially inwardly. Thereby, the longitudinal extensions can at least partially close the central lumen 334 substantially adjacent to the distal end region of the cover member 330.

Referring back to FIGURE 9, in operation, the tube set 305 of the delivery assembly 200 of the clip applier apparatus 100 is advanced through the sheath lumen 644 of the sheath 640 using similar techniques to those shown and described in FIGURES 8A and 8B. When the tissue locator portion 202 locates the vessel opening 610 and the bleed back shaft 260 is inserted into the body vessel 600 to the predefined depth, the bleed back port 262 communicates with fluid flow, hence locating the vessel opening 610.

Once tissue locator portion 202 is properly oriented, the tissue engaging device 400 can be distally deployed from a distal end of the tubular body 210. As shown in FIGURES 10 and 11, the tissue engaging device 400 is slidably disposed within a lumen 204 of the tubular body 210. This lumen 204 further extends through the carrier assembly 300 and the locator portion 202, terminating at an end port 264 at the distal end thereof. The tissue engaging device 400 includes one or more tongs 410 having proximal end regions associated with a common control shaft (not shown) operated at the handle portion 380 of the clip applier apparatus 100. Each resilient tong 410 is naturally bowed in a U-shaped manner such that when continually distally advanced from the tubular body end port 264, each tong resiliently bows radially outwardly from common axis 216, and bows upwardly toward the interior surface 620b of the opposing arterial walls 620', 620". As the tongs 410 of the tissue engaging device are further deployed, the tips 412 (e.g., barbed tips) of the tongs 410 are configured to intravascularly pierce, snare or grab the arterial walls 620', 620" from the underside surface 620b surrounding the puncture site

(i.e., in a tissue engaging condition of FIGURE 9). The snaring, piercing and/or grabbing of the arterial walls could be accomplished by hooks, barbs, or similar on the ends of the tongs 410. The piercing from the underside surface, furthermore, may be accomplished by the curved shape of the tongs 410 as they exit the distal end of the bleed back shaft 260.

Accordingly, the resilient tongs 410 are sufficiently flexible for sliding reciprocal receipt in the receiving lumen 204 of the tubular body 210 of the delivery assembly 200, yet sufficiently rigid to enable piercing, snaring or grabbing of the arterial walls when engaged therewith. Such materials exhibiting these characteristics, for example, include Nitinol and stainless steel.

Once the opposing arterial walls 620', 620" are sufficiently grasped, snared or penetrated, the tubular body 210 of the delivery assembly 200 is retracted extravascularly through the receiving lumen 204 of the pusher member 320. This operation is performed while the garage tube 330, the closure element 500" and the pusher member 320 are substantially axially maintained at their position relative to the vessel opening 610 of the body vessel 600. Accordingly, the relative movement between the tubular body 210 and the pusher member 320, in turn, unseats the closure element 500" from the carrier seat 302 and advances it toward the distal end of the tubular body 210. Alone or in combination with the above tubular body retraction, the tongs 410 of the tissue engaging device 400 may also be retracted into the receiving lumen 204 of the tubular body 210. As the tubular body 210 and/or the tongs 410 are being retracted, the arterial walls 620', 620" are pulled together radially inward until they are disposed within the first diameter of the closure element 500", in a closing condition (FIGURE 10). Continued retraction further urges the engaged opposing arterial walls 620', 620" radially together under the bleed back shaft and into the channel 540 defined by the substantially tubular closure element 500".

To permit the substantially tubular closure element 500" to be deployed from the annular cavity 360, the cover member 330 can also be slidably retracted, relative the tubular body 210. The longitudinal extensions 335 of the cover member 330 preferably are sufficiently flexible to expand radially to permit retroactive movement of the distal end region of the cover member 330 peripherally over the mounted closure element 500". This opens the annular cavity 360 such that the distal end region of the cover member 330 no longer fully encloses the closure element.

Turning now to FIGURE 11, the pusher member 320 is then advanced distally to deploy the closure element 500". Similar to the technique applied above, the tines 520 of the closure element 500" pierce the opposing arterial walls 620', 620" that are radially pulled together, via the tissue engaging device 400 in the closing condition, within the 5 first diameter. Once the substantially tubular closure element 500" is deployed, it begins to transition from the tubular configuration to the natural, planar configuration with opposing tines 520 and a natural cross-section 530 of the closure element 500 (substantially similar to the deployment of the closure element detailed and shown in FIGURES 8G and 8H). The arterial walls 620', 620" are drawn substantially closed 10 and/or sealed as the cross-section 530' of the substantially tubular closure element 500" contracts to return to the natural cross-section 530 of the closure element 500. Thereby, the opening 610 in the blood vessel wall 620 can be drawn substantially closed and/or sealed via the closure element 500, as illustrated in FIGURE 8H. Subsequently, the tongs 410 of the tissue engaging device 400 are retracted in the bleed back shaft 260, and the 15 delivery assembly 200 and sheath 640 can be removed.

It will be appreciated that the bleed back shaft 260 is composed of a material that reduces sticking of the tines 520 of the closure element during deployment, should any contact ensue. This would be detrimental, of course to the proper clip deployment. Essentially, the composition should be at least as hard as the tines of the closure element 20 so as not to stick into the bleed back shaft itself. Beneficial shaft compositions include any hard material that can be formed into a tube and is also biocompatible, such as stainless steel and Nitinol to name a few. Further, similar to the embodiments above-mentioned, the seating of the closure element 500" about the carrier seat 302 is in a manner angularly off-setting the closure element tines 520 (relative to the longitudinal 25 axis 216) from the angular position of the tissue engaging tongs 410, to reduce interference during deployment of the closure element.

FIGURES 12 and 13 represent another specific embodiment clip applier apparatus 100 incorporating a tissue engaging device 400 that intravascularly engages the opposing arterial walls 620', 620". In accordance with this specific embodiment, however, the 30 analogous tongs 410 cooperate to radially push the engaged opposing arterial walls together as opposed to radially pulling them together, as does the embodiment disclosed in FIGURES 9-11. As best illustrated in FIGURE 12, the tongs 410 of the tissue engaging device 400, in their natural configuration, are substantially C-shaped. For each tong 410, the respective distal tip 412 is configured to loop nearly all the way around onto

itself. That is, in their respective own plane substantially intersecting the longitudinal axis 216 of the bleed back shaft 260, the distal tip of each tong loops back around from the end port 264 of the bleed back shaft 260. Briefly, it will be appreciated that natural loop shape of each tong neither needs to be exactly circular, nor be curvilinear for that matter, as long as the tip 412 extends back around in a direction toward the longitudinal axis 216 of the shaft 260.

Again, using similar placement and advancement techniques through the sheath lumen 644 of the sheath 640, as show and described in FIGURES 8A and 8B, the tube set 305 of the delivery assembly 200 can be positioned near the vessel opening 610. Once 10 the tissue locator portion 202, via bleed back port 262, has determined the location and proper depth of insertion of the bleed back shaft 260 into the vessel opening 610 of the vessel body 600, the two or more tongs 410 are advanced distally out of the shaft end port 264, via controls at the handle member 380 (FIGURE 6). As the advancement of the 15 tongs 410 of the tissue engaging device 400 distally continue, the tips 412 of the tongs 410 continue to loop back around until they grip, snag and/or partially pierce the underside surface 620b the in opposing arterial walls 620', 620" (in a manner similarly described in the operation of the embodiment of FIGURES 9 and 10).

Once the arterial walls 620', 620" are sufficiently initially engaged, further advancement of the tongs from the distal end port 264 of the bleed back shaft 260 causes 20 the tong tips 412 to return to their natural state, in their respective plane (i.e., directed back toward longitudinal axis 216 of the bleed back shaft 260). In effect, the engaged opposed arterial walls 620', 620" are pushed together by the advancing tong tips 412, which return to their natural state, until the edges 622', 622" of the opposing arterial walls 620', 620" contact the exterior surface of the bleed back shaft 260. Accordingly, unlike 25 the previous embodiment, the engaged opposing arterial walls 620', 620" are urged together without retracting the bleed back shaft 260 and/or retracting the tongs 410 back into the receiving lumen 204. This is beneficial in that it allows the user to continue monitoring the proper location of the device. Further, by not retracting the tongs, the chance that the tongs dislodge from the arterial walls decreases prior to deployment of the 30 closure element.

Accordingly, the tips 412 of the respective tongs 410 are configured to not fully penetrate the engaged opposing arterial wall 620', 620" or each tong may experience difficulty urging and pushing the opposing walls back toward and against the bleed back

shaft. For example, the tip configuration can be more blunted, radiused or roughened, so as to partially pierce the tissue, but not fully penetrate it.

Regarding the resilient tongs 410, they must be capable of sufficient flexibility to unfold from their naturally curved and hooked configuration to a substantially straight configuration when housed or stored within the lumen 204 of the tubular body 210. However, the tongs 410 of the tissue engaging device 400 must also be sufficiently stiff, strong and resilient to push the engaged arterial walls together, and back against the bleed back shaft 260 when the tongs are fully deployed from the distal end of the bleed back shaft 260. Such materials for each tong 410, for example, may include Nitinol and stainless steel.

Since the opposed arterial walls 620', 620" must be pushed, as opposed to pulled, radially together to an orientation within the first diameter of the seated closure element 500", the diameter of the bleed back shaft 260 at the region of contact by the edge 622', 622" of the arterial walls 620', 620" is reduced from that of the carrier seat 302. Such a diameter reduction, relative to the carrier seat, increases the width of tissue engagement about by the tines 520 of the closure element 500", about the vessel opening 610, by enabling the opposed arterial walls to be pushed closer together.

Referring now to FIGURE 14, the pusher member 320 may be distally advanced to engage the seated closure element 500", in the substantially tubular condition, during deployment. The delivery assembly 200, and hence the bleed back shaft 260, are axially maintained in position during the deployment of the closure element 500". Once the substantially tubular closure element 500" is deployed, it begins to transition from the tubular configuration to the natural, planar configuration with opposing tines 520 and a natural cross-section 530 of the closure element 500 (substantially similar to the deployment of the closure element detailed and shown in FIGURES 8G and 8H). Again, the opening 610 in the blood vessel wall 620 can be drawn substantially closed and/or sealed via the closure element 500" as illustrated in FIGURE 8H. Subsequently, the tongs 410 of the tissue engaging device 400 are retracted in the bleed back shaft 260, and then the bleed back shaft 260 is retracted from the "closed" opening 610 of the puncture site.

It will again be appreciated that the bleed back shaft 260 is composed of a material that reduces sticking of the tines 520 of the closure element therewith during deployment and withdrawal of the shaft from the opening, should any contact ensue. As mentioned above, beneficial shaft compositions include any hard material that can be

formed into a tube and is also biocompatible, such as Nitinol and Stainless steel. Furthermore, the seating of the closure element 500" about the carrier seat 302 is in a manner angularly off-setting the closure element tines 520 (relative to the longitudinal axis 216) from the angular position of the tissue engaging tongs 410, to reduce 5 interference during deployment of the closure element.

Referring now to FIGURE 15, another specific embodiment of the clip applier apparatus 100 is illustrated that is structurally and functionally similar to the clip applier apparatus embodiment detailed in FIGURES 9-11. In this specific embodiment, however, the cover member or garage tube 330 shown in the embodiment of FIGURE 9 is 10 removed, providing a significantly reduced diametric footprint for the tube set 305 of the delivery assembly 200. Accordingly, during advancement of the delivery assembly to the vessel opening 610, via the lumen 644 of the sheath 640, protection of the seated closure element 500" is afforded by the sheath itself.

As above-mentioned, the diametric footprint of the clip applier apparatus 100 in 15 this specific embodiment is further reduced by an amount equivalent to the removal of the garage tube from the tube set 305. Hence, the tube set 305 of the delivery assembly only includes the pusher member 320 of the carrier assembly 300, and the tubular body 210. The tubular body 210, which supports the carrier seat 302, the tissue locator assembly 202 and the tissue engaging device 400 supported within the receiving tubular body lumen 20 204, may similarly be capable of axial displacement, relative to the sheath 640, the pusher member 320 and the closure element 500", in the substantially tubular configuration.

Furthermore, the introducer sheath 640 will selected to cooperate with the tube set 305 of the delivery assembly 200 in a manner similar to the cooperation between the garage tube 330 and the pusher member 302 and closure element 500" of the previous 25 embodiments. That is, the interior diameter of the sheath lumen 644 should be sized to cooperate with the exterior diameter of the pusher member 320 and the seated closure element 500" to permit sliding axial displacement therebetween, yet be sufficiently snug at the distal tip to retain the closure element in the substantially tubular configuration until it is released out of its distal thereof.

30 Referring back to FIGURE 15, the tissue engaging device 400 of this embodiment is illustrated incorporating a similar device to that described in the embodiment of FIGURES 9-11 (i.e., centrally deployed resilient tongs 410). It will be appreciated, however, that any tissue engaging device could be incorporated that is functionally capable of engaging and urging the opposed arterial walls 620', 620" together and

radially within the first diameter of the closure element 500" (about longitudinal axis 216).

Again, similar to the operation of the embodiment of FIGURES 9-11, once the tissue locator portion 202 is properly oriented, the tissue engaging device 400 can be distally deployed from a distal end of the tubular body 210. The tissue engaging device 400 includes one or more tongs 410 having proximal end regions associated with a common control shaft (not shown) operated at the handle portion of the clip applier apparatus 100. Each resilient tong 410 is naturally bowed in a U-shaped manner such that when continually distally advanced from the tubular body end port 264, each tong 10 resiliently bows radially outwardly from common axis 216, and bows upwardly toward the interior surface 620b of the opposing arterial walls 620', 620". Once the tongs 410 of the tissue engaging device are sufficiently anchored to the corresponding arterial walls 620', 620" (in the tissue engaging condition similar to that shown in FIGURE 9), the tubular body 210 and/or the tongs 410 are retracted, while the pusher member 320 and the 15 closure element 500" are substantially maintained, axially. Similar to the closing condition of FIGURE 10 and as shown in FIGURE 15, the engaged opposing arterial walls 620', 620" are drawn and urged together, radially inward toward one another until they are disposed within the first diameter of the closure element 500". Continued retraction further urges the engaged opposing arterial walls 620', 620" radially together 20 under the bleed back shaft and into the channel 540 defined by the substantially tubular closure element 500".

The pusher member 320 is then advanced distally to deploy the closure element 500" off of the end of the obturator or tissue locator device 202, and out of the lumen 644 of the introducer sheath 640. The distally directed tines 520 of the closure element 500" 25 pierce the opposing arterial walls 620', 620" that are radially pulled together, via the tissue engaging device 400 in the closing condition, within the first diameter. Once the substantially tubular closure element 500" is deployed, it begins to transition from the tubular configuration to the natural, planar configuration with opposing tines 520 and a natural cross-section 530 of the closure element 500 (substantially similar to the deployment of the closure element detailed and shown in FIGURES 8G and 8H). The arterial walls 620', 620" are thus drawn substantially closed and/or sealed. Subsequently, the tongs 410 of the tissue engaging device 400 are retracted in the bleed back shaft 260, and the delivery assembly 200 and sheath 640 can be removed.

The present invention has been described using various element identifiers to represent elements in the figures. It should be considered that the element identifiers described in connection with a particular figure may be shown in a different figure for purposes of clarity. Thus, the element identifiers described in connection to a particular 5 figure may be illustrated in a different figure for clarity because the same element identifiers have been used to describe the same elements.

The invention is susceptible to various modifications, alternative forms and uses, and specific examples thereof have been shown by way of example in the drawings and are herein described in detail. For instance, while the present invention has been 10 primarily described for use in vessel closure, it will be appreciated that the present invention may be suitable for other repair applications as well, such as for patent foramina ovalia (PFO) application. Other modifications may include a guide wire lumen so that the distal ends may be positioned over a guide wire as well. It should be understood, however, that the invention is not to be limited to the particular forms or 15 methods disclosed, but to the contrary, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the claims.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the 20 invention is, therefore, indicated by the appended claims rather than by the foregoing description.

## CLAIMS

What is claimed is:

1. An apparatus for positioning a closure element to close an opening in a body lumen, the apparatus comprising:
  - 5 a carrier assembly configured to support a closure element in a substantially tubular configuration in a first diameter, the closure element being configured to substantially uniformly deform from a substantially tubular configuration to a natural, substantially planar configuration; and
    - a distal tissue engaging device selectively axially displaceable relative to at least a portion of said carrier assembly between a tissue engaging condition, engaging opposing portions of an arterial wall defining said body lumen adjacent to said opening, and a tissue closing condition, urging the engaged the opposing portions of said arterial wall substantially together such that the closure element may be deployed from the delivery assembly to engage said opposed portions of said arterial wall and to return to said natural, substantially planar configuration.
  - 10 2. The apparatus of claim 1, wherein said distal tissue engaging device includes two or more opposed engaging tongs having respective end tips configured to open radially in directions extending beyond the first diameter to initially engage the opposing portions of the arterial wall, in the engaging condition.
  - 15 3. The apparatus of claim 1, wherein said carrier assembly further includes a cover member protecting at least said closure element which is contained therein.
  4. The apparatus of claim 3, wherein said distal tissue engaging device is integral with a distal end of said cover member.
  - 20 5. The apparatus of claim 1, wherein said carrier assembly is formed and dimensioned for sliding axial, reciprocating, receipt in a lumen of an introducer sheath extending through said tissue and terminating proximate the opening, and said tissue engaging device being configured to cooperate with the introducer sheath to enable movement between the engaging condition and the closing condition.
  - 30 6. An apparatus for delivering and deploying a substantially resilient closure element through tissue to an opening in a body lumen peripherally defined by opposing arterial walls, the closure element being configured to substantially uniformly deform from a natural, substantially resilient planar configuration to a substantially tubular configuration, having a substantially natural transverse cross-sectional dimension, said apparatus comprising:

a delivery assembly positionable through said tissue toward the opening in the body lumen, the delivery assembly having a distal tissue engaging device and a carrier assembly configured to support said closure element in the substantially tubular configuration in a first diameter, said distal tissue engaging device being selectively 5 axially displaceable relative to at least a portion of said carrier assembly between a tissue engaging condition, engaging the opposing arterial walls of said body lumen adjacent to said opening, and a tissue closing condition, urging the engaged opposing arterial walls substantially transversely together such that the closure element may be deployed from the delivery assembly, while substantially maintained in the first diameter, into the 10 opposing arterial walls;

wherein said closure element is oriented to engage said engaged opposing arterial walls when deployed and to return to said natural, substantially planar configuration and said natural, transverse cross-sectional dimension such that the engaged opposing arterial walls are drawn substantially closed.

15 7. The apparatus of claim 6, further comprising a locator to position the carrier assembly and distal tissue engaging device adjacent to the opening in the body lumen, the locator having a distal locator portion selectively controllable between an unexpanded state and an expanded state for engaging the opposing portions of the arterial wall of said body lumen.

20 8. The apparatus of claim 6, further including a distal tissue locator portion contained on said delivery assembly, and configured to facilitate detection of the body lumen, said distal locator portion including one or more expansion elements configured to expand substantially transversely with respect to a longitudinal axis of the distal locator portion.

25 9. The apparatus of claim 8, wherein said distal locator portion is selectively controllable between an unexpanded state and an expanded state for engaging said opposing arterial walls of said body lumen.

10. The apparatus of claim 9 wherein in said unexpanded state, said distal locator portion has a transverse cross-sectional dimension less than that of said opening, and in 30 said expanded state, said distal locator portion has a transverse cross-sectional dimension greater than or substantially equal to that of said opening.

11. An apparatus for positioning a closure element to close an opening in a body lumen, the apparatus comprising:

a carrier assembly having a tubular body configured to receive a closure element in a substantially tubular configuration in a first diameter prior to deployment, said tubular body having a distal port; and

5 a distal tissue engaging device disposed within said tubular body and selectively axially displaceable from said distal port, a portion of said distal tissue engaging device being biased to selectively radially extend outwardly from a longitudinal axis of said tubular body to intravascularly engage opposing arterial walls of the body lumen, said portion of said distal tissue engaging device urging the engaged opposing portions of the arterial wall substantially together as said distal tissue engaging device  
10 moves proximally and said the closure element is deployed to engage the opposed portions of the arterial wall.

12. The apparatus of claim 11, wherein said carrier assembly includes a cover member defining a lumen configured for slidable receipt of said closure element therein.

13. The apparatus of claim 11, wherein said carrier assembly includes a pusher member slidably for distally deploying said closure element.  
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14. The apparatus of claim 13, wherein said pusher member and said tubular body are disposed as a nested, telescoping tube set with a common longitudinal axis.

15. The apparatus of claim 11, wherein said tubular body comprises a tissue locator portion , said tissue locator portion including a bleed back shaft having a bleed back port distally disposed on a distal end of the tubular body.  
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16. A closure system for closing an opening formed in a body lumen peripherally defined by opposing arterial walls, said system comprising:

25 a closure element adapted to deform from a natural, substantially resilient planar configuration to a substantially tubular configuration, having a substantially natural transverse cross-sectional dimension;

a delivery assembly positionable through said tissue and into the opening in the body lumen, and having an elongated body, a carrier assembly and a distal tissue engaging device, said carrier assembly including a carrier seat configured to carry and peripherally support said closure element in the substantially tubular configuration, in a first diameter, and said distal tissue engaging device selectively axially displaceable relative to said carrier seat between an engaging condition, engaging the opposing arterial walls of said body lumen adjacent to said opening, and a closing condition, urging the engaged opposing arterial walls substantially transversely together such that the closure  
30

element may be deployed from the carrier assembly, while substantially maintained in the first diameter, into the opposing arterial walls; and

a pusher member slidably disposed about said elongated body for relative axial sliding displacement therebetween, said pusher member having a contact portion disposed proximally adjacent the closure element to selectively distally deploy said closure element from said carrier assembly, in the substantially tubular configuration, to engage said opposing arterial walls and to return to said natural, substantially planar configuration and said natural, transverse cross-sectional dimension such that the engaged opposing arterial walls are drawn substantially closed.

10 17. The closure system of claim 16, wherein said delivery assembly includes a tubular body supporting said carrier seat, and defining a central receiving lumen extending longitudinally therethrough that is configured for sliding support of the tissue engaging device for axial movement between the engaging condition and the closing condition.

15 18. The closure system of claim 16, wherein said pusher member comprises one or more distally extending longitudinal extensions.

19. The closure system of claim 16, further comprising a locator slidably receivable within said pusher member and said delivery assembly.

20. A method for closing an opening defined by edges of arterial walls of a body lumen, the method comprising:

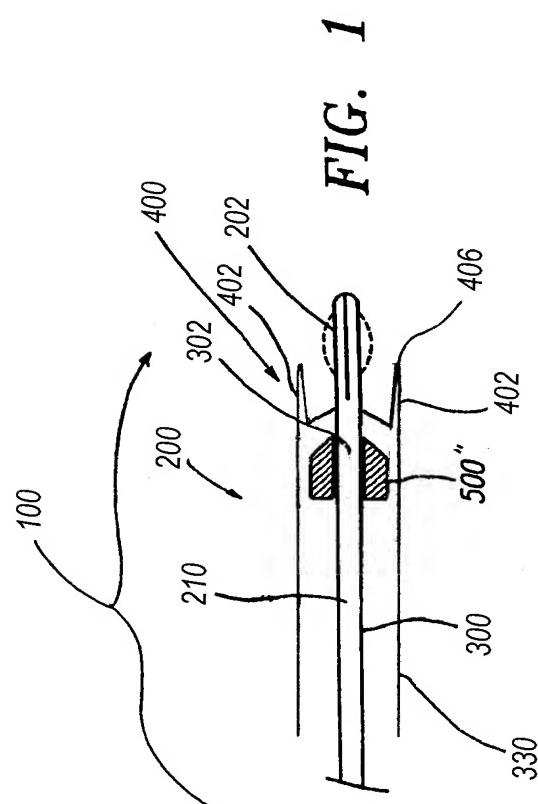
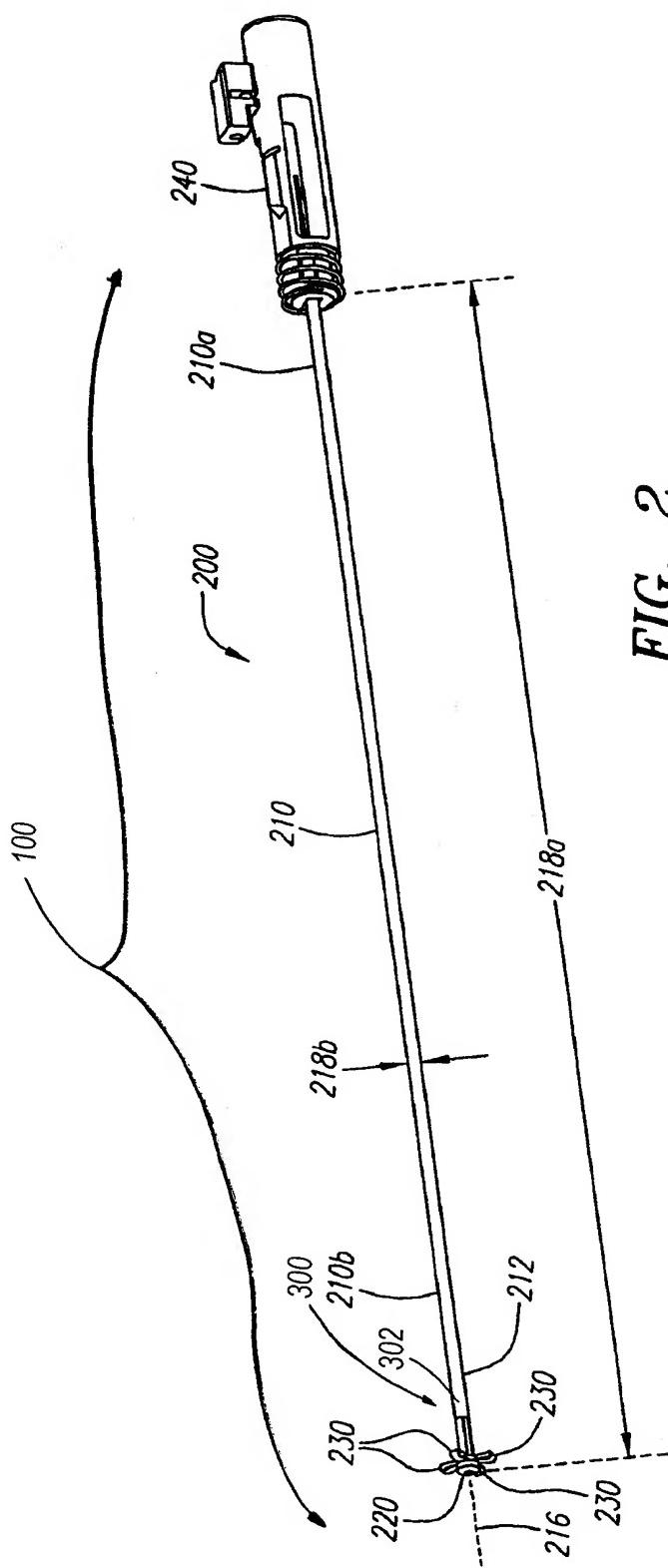
20 positioning a distal end region of a carrier assembly through tissue adjacent to an opening so that a distal tissue engaging device engages opposing portions of arterial walls, said distal end region of said carrier assembly including a carrier seat configured to seat said closure element thereon in a substantially tubular configuration, having a first diameter;

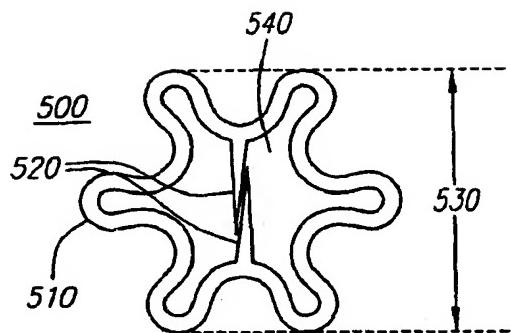
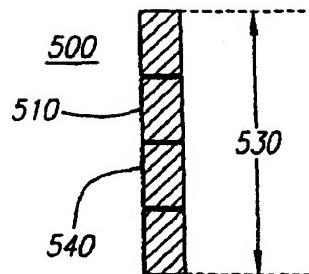
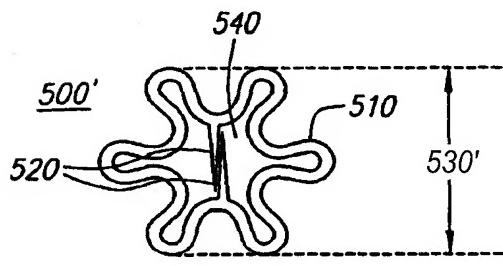
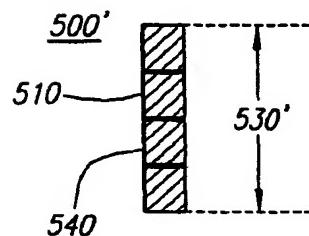
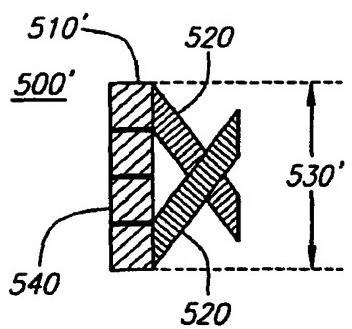
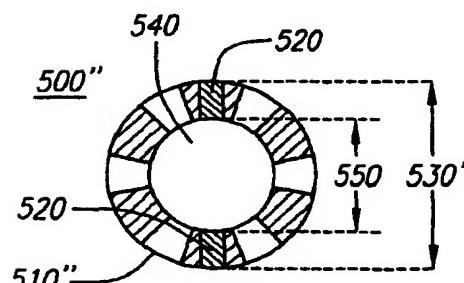
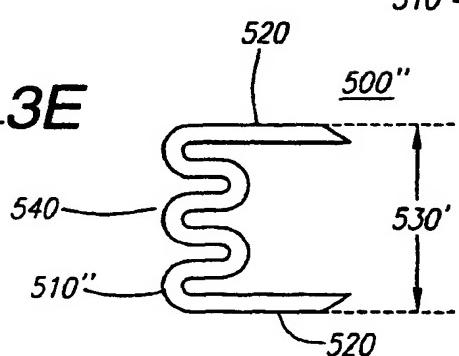
25 urging the engaged arterial walls radially inwardly and toward one another such that at least opposed edges of the arterial walls drawn with the first diameter of the closure element; and

30 distally deploying said closure element from said carrier assembly without further substantial radial expansion for said closure element, in the substantially tubular configuration, such that said closure element engages the arterial walls, and returns to said natural, planar configuration and said natural cross-section wherein the tissue is drawn substantially closed.

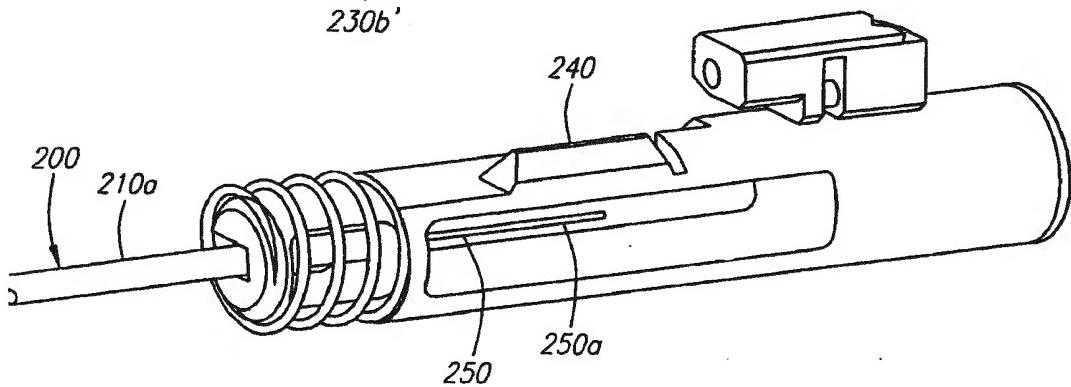
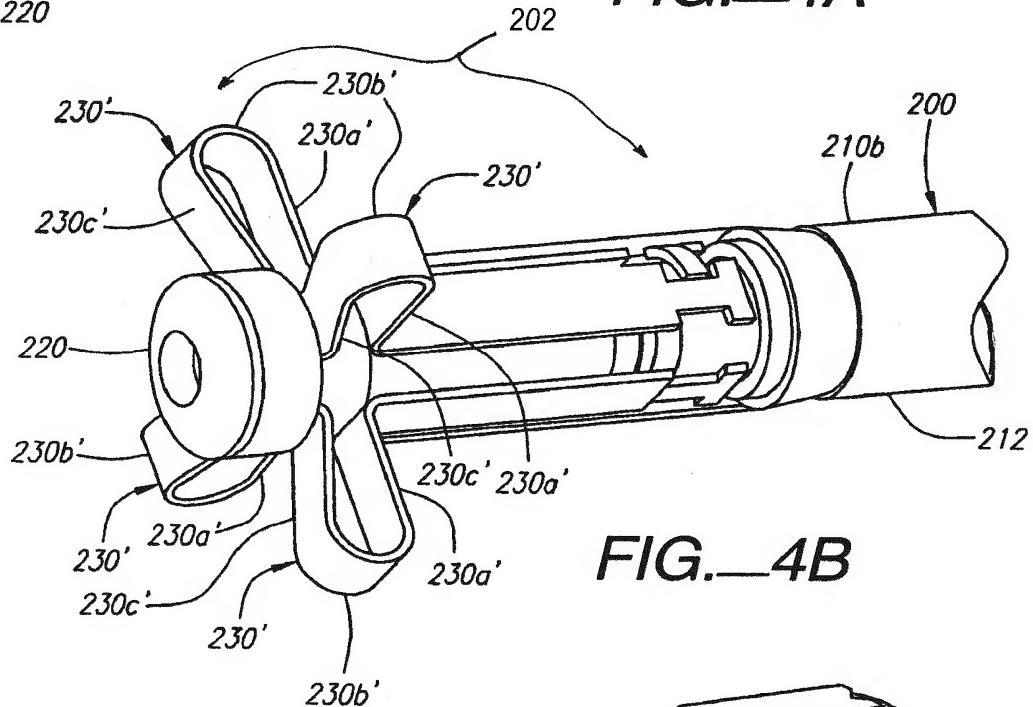
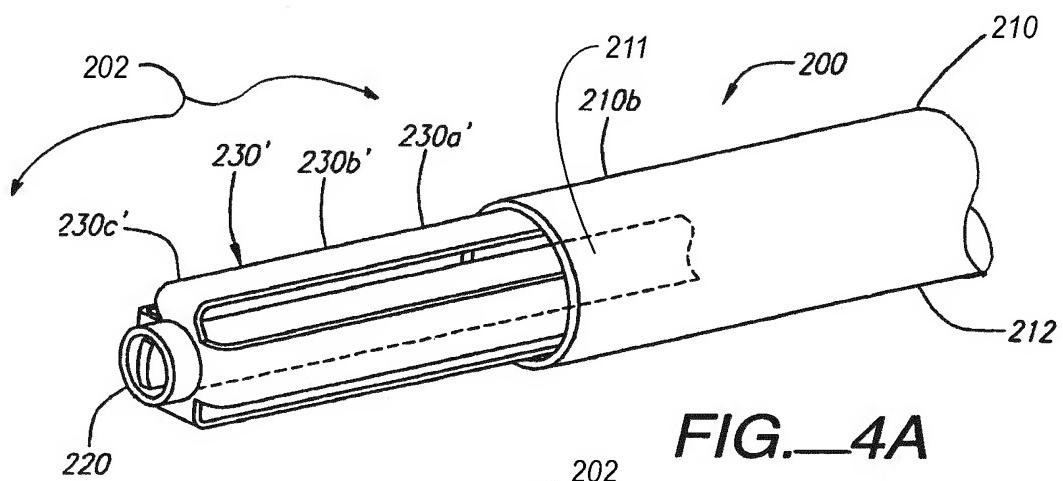
21. The method according to claim 20, wherein, said engaging the arterial walls is performed by extravascularly engaging the arterial walls with the tissue engaging device.

22. The method according to claim 20, wherein, said engaging the arterial walls is performed by intravascularly engaging the arterial walls with the tissue engaging device.
23. The method as recited in claim 20, further comprising placing a distal end region of a locator portion through tissue into the opening.
- 5 24. The method as recited in claim 20, further comprising engaging the arterial walls adjacent to the opening.
25. The method as recited in claim 20, further comprising orientating said carrier assembly proximal to said locator portion.

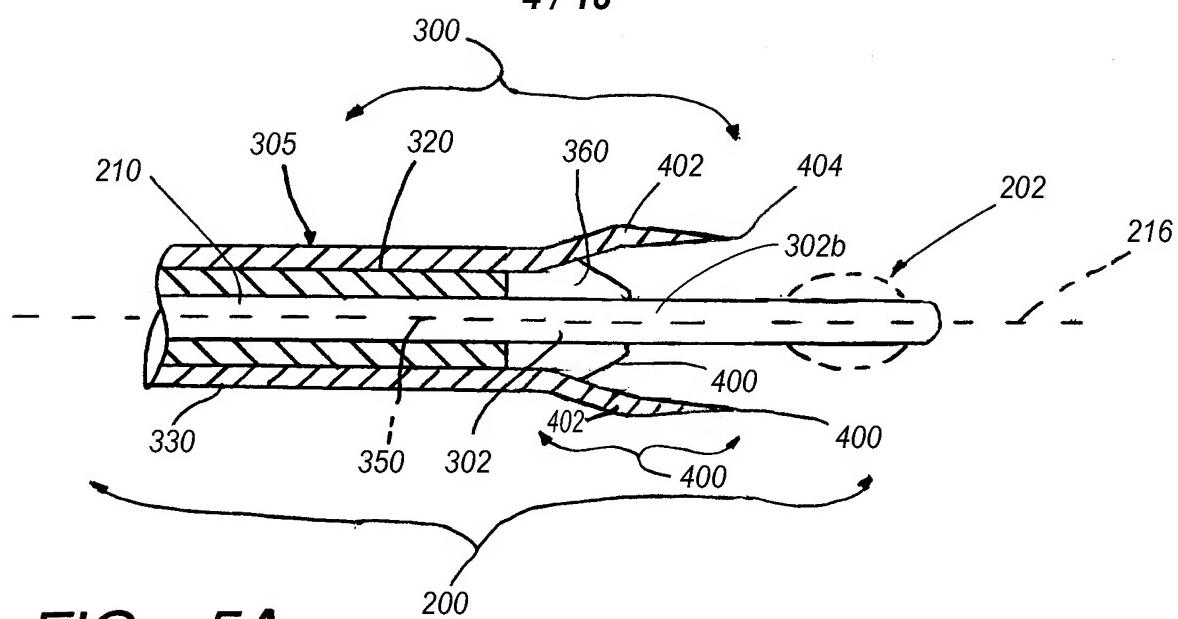
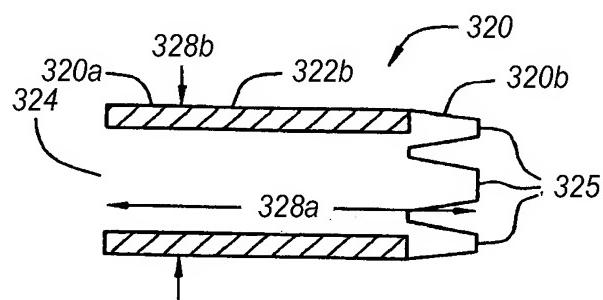
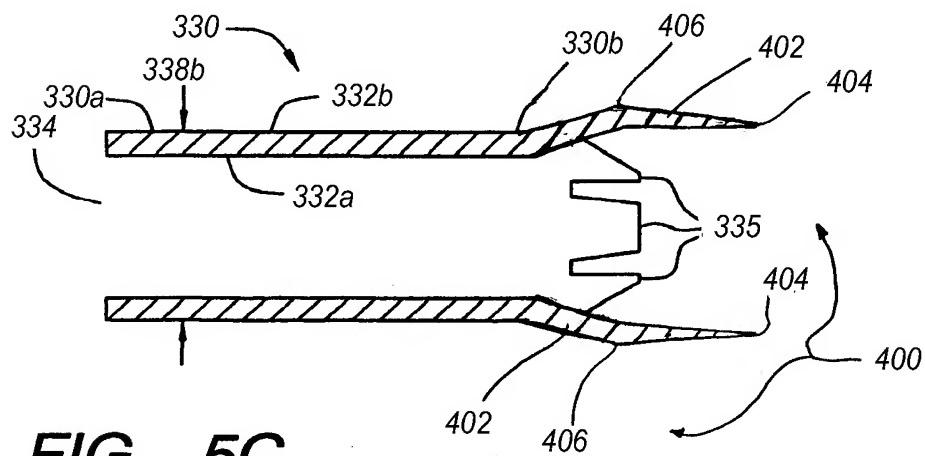


**FIG. 3A****FIG. 3B****FIG. 3C****FIG. 3D****FIG. 3E****FIG. 3F****FIG. 3G**

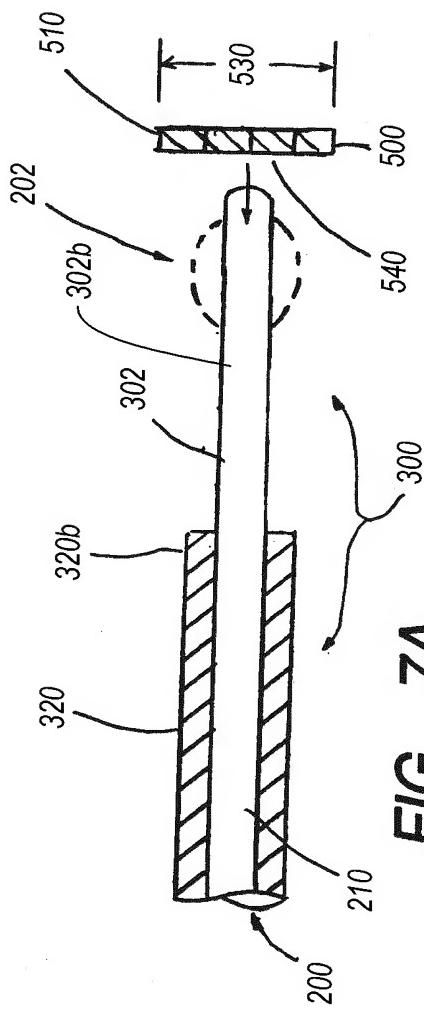
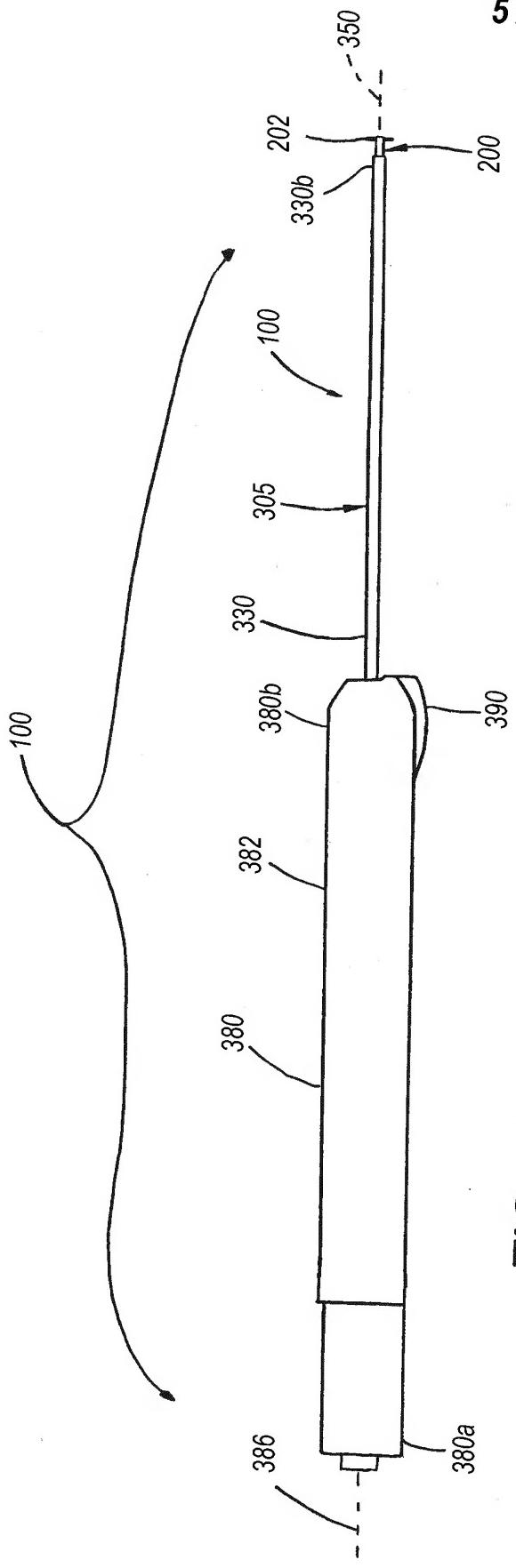
3 / 18



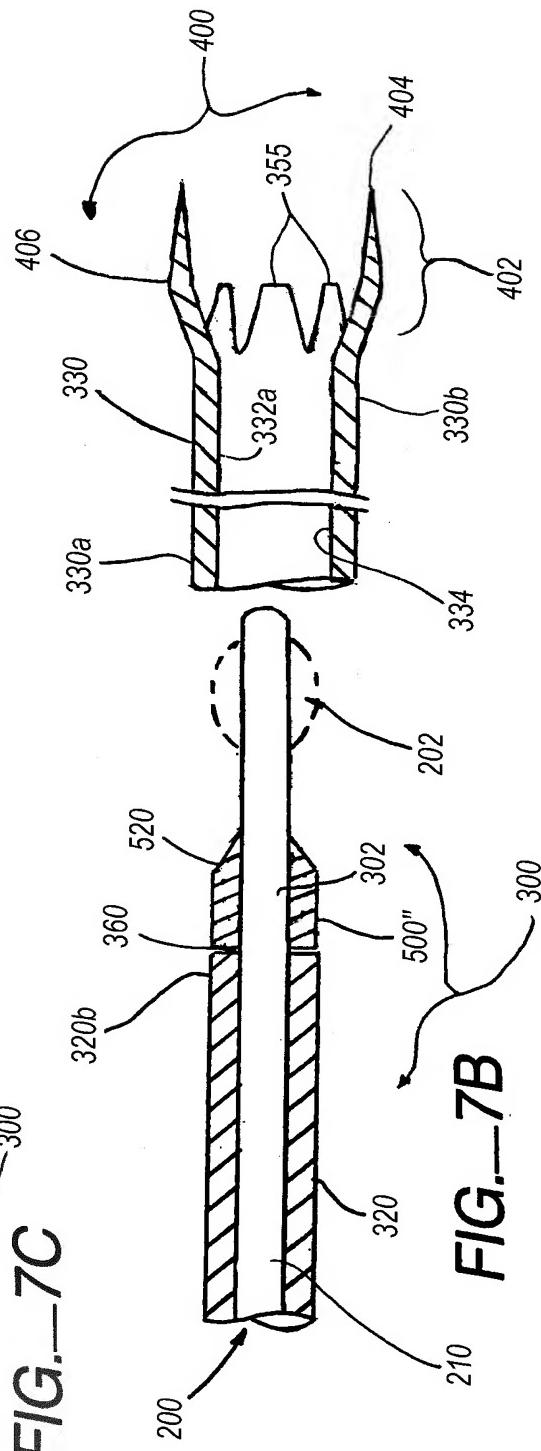
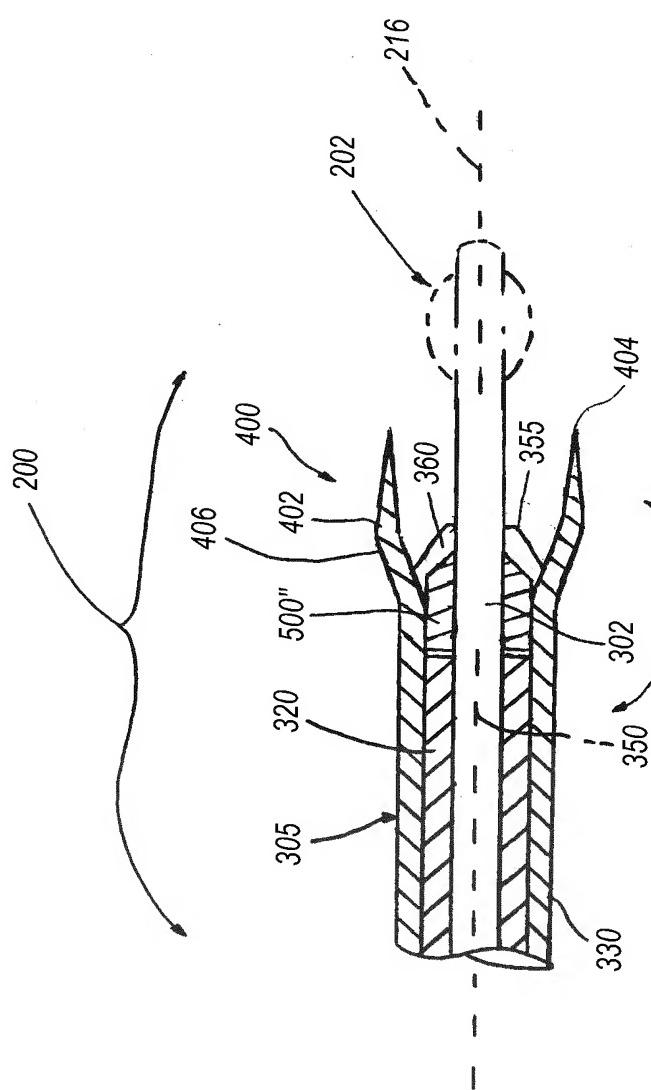
4 / 18

**FIG. 5A****FIG. 5B****FIG. 5C**

5 / 18



6 / 18



7 / 18

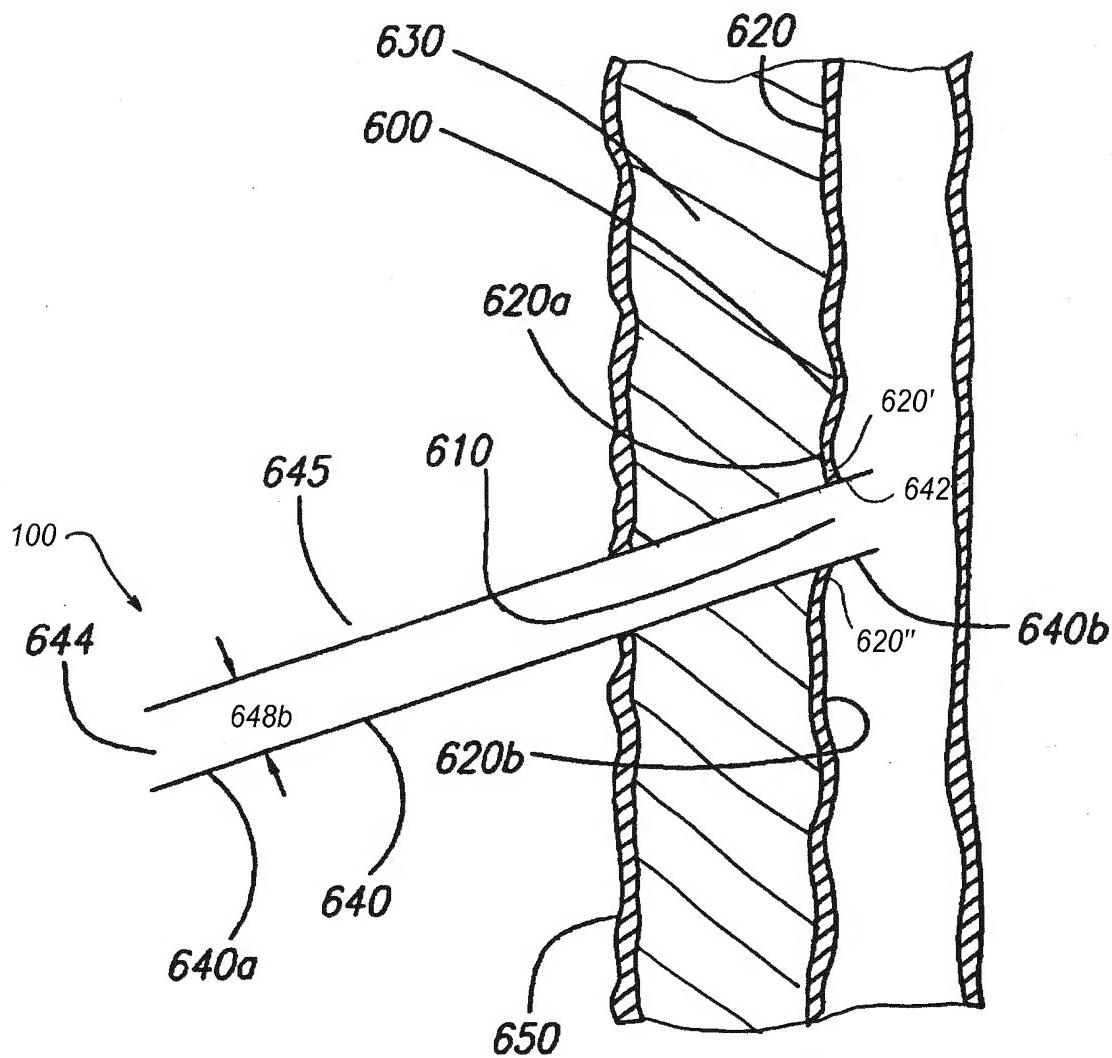


FIG.—8A

8 / 18

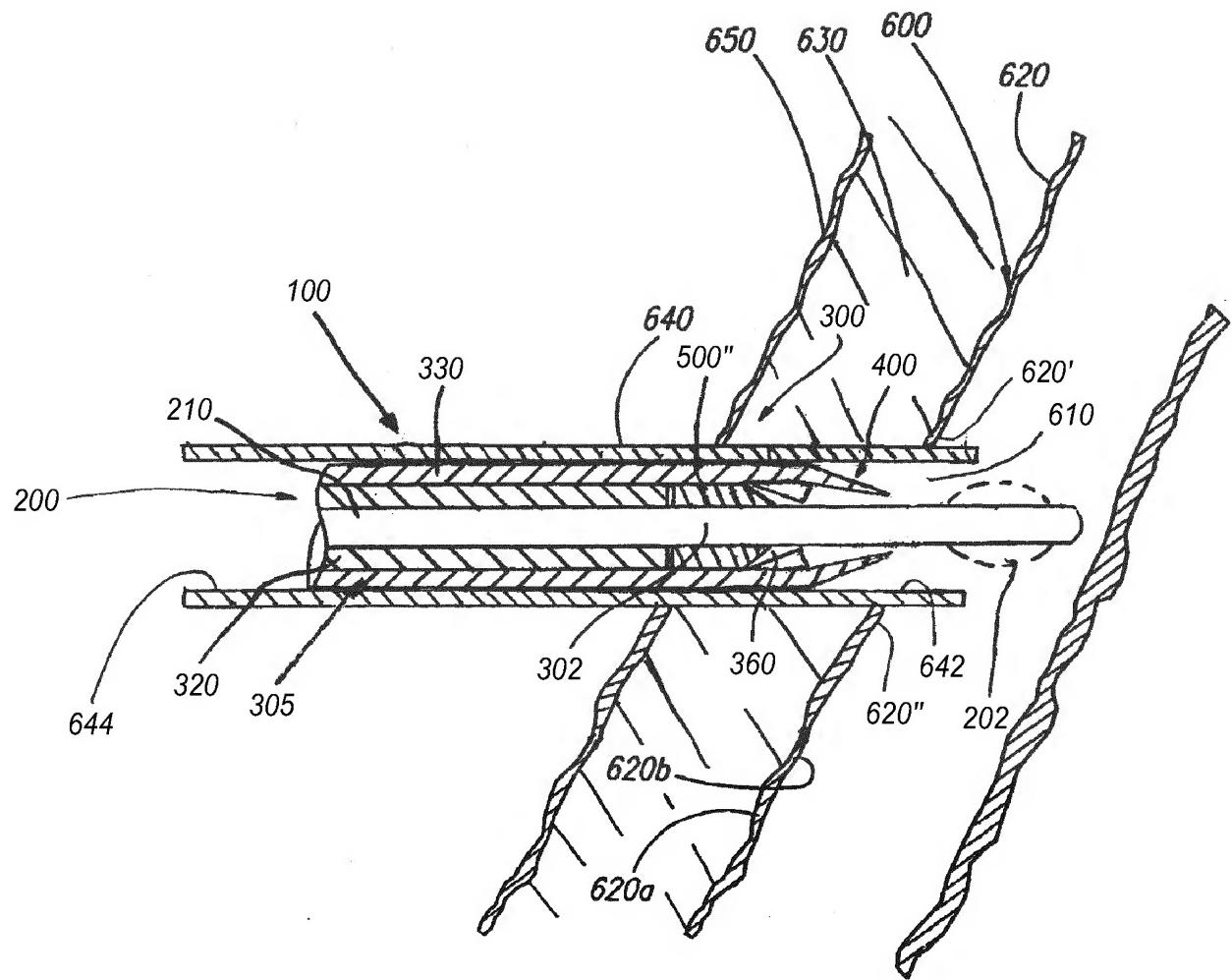


FIG. 8B

9 / 18

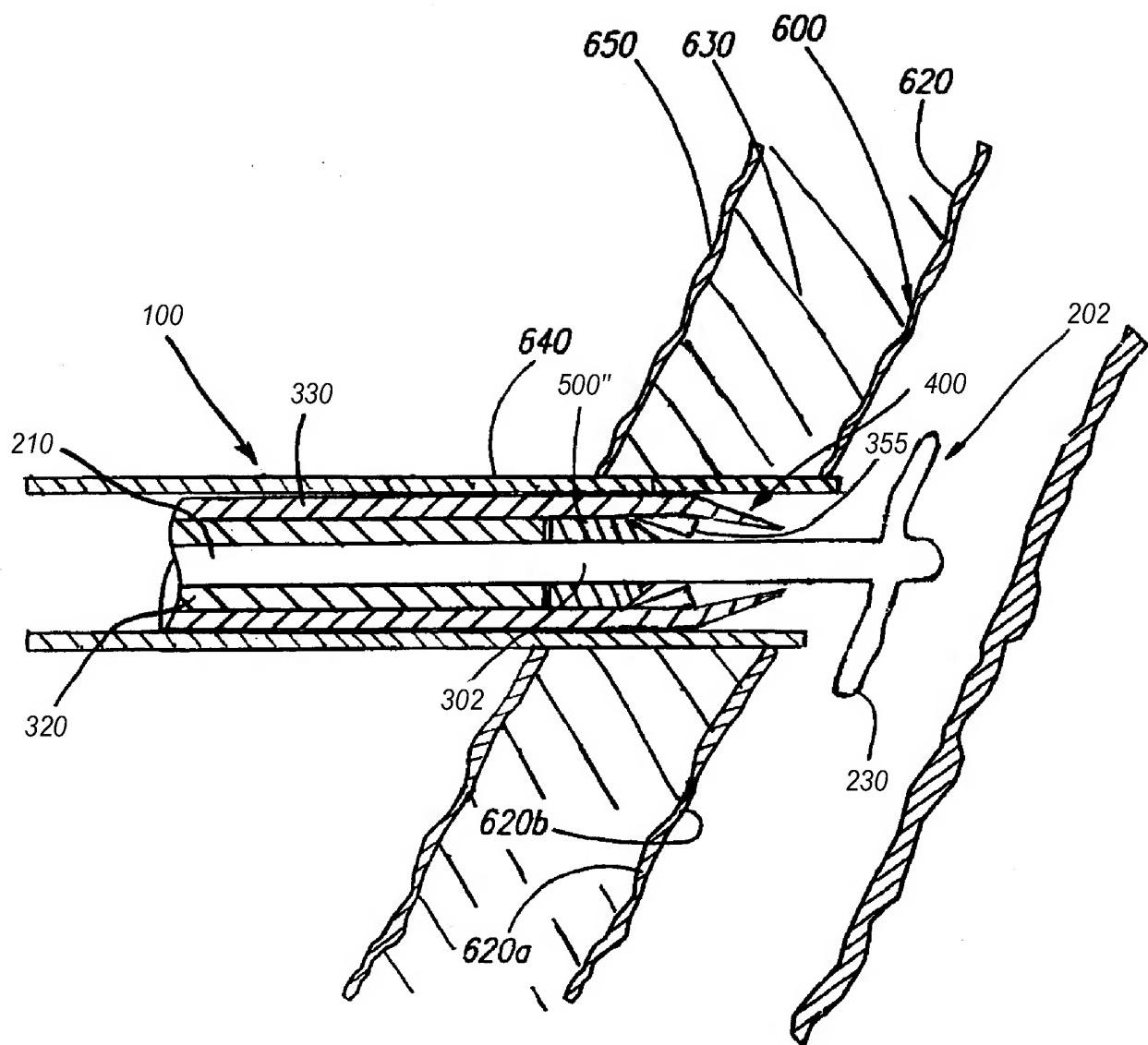


FIG. 8C

10 / 18

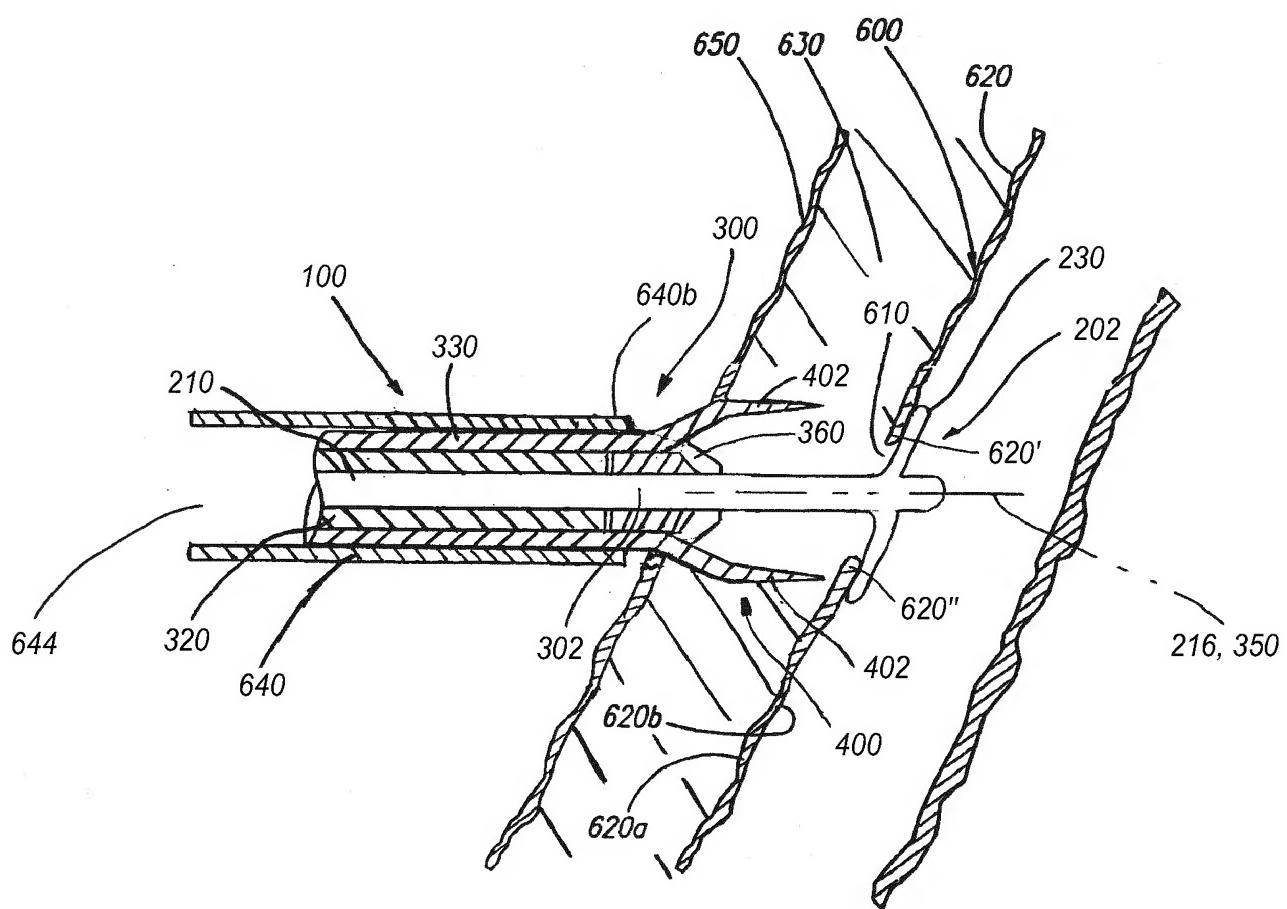


FIG. 8D

11 / 18

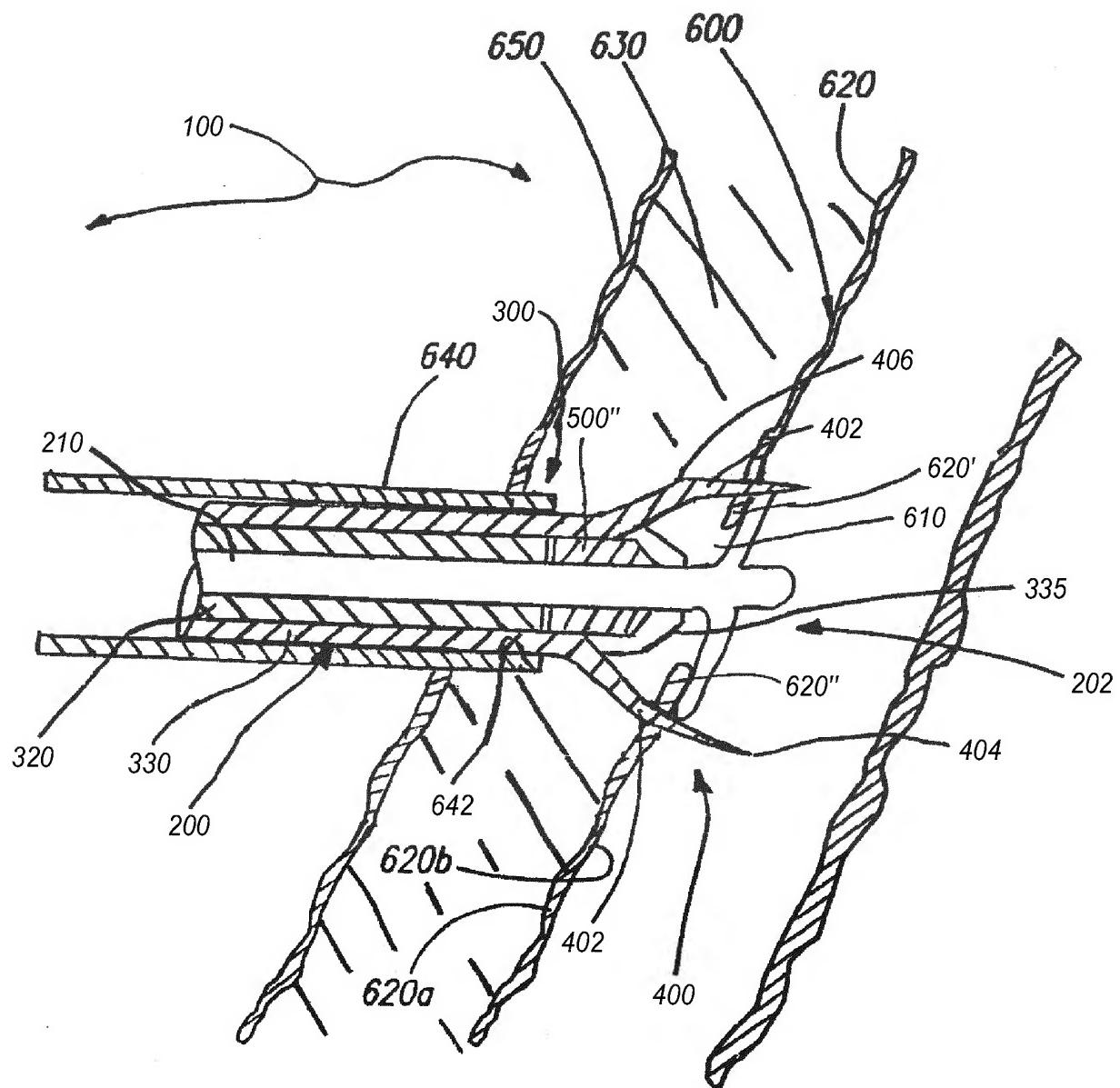


FIG. 8E

12 / 18

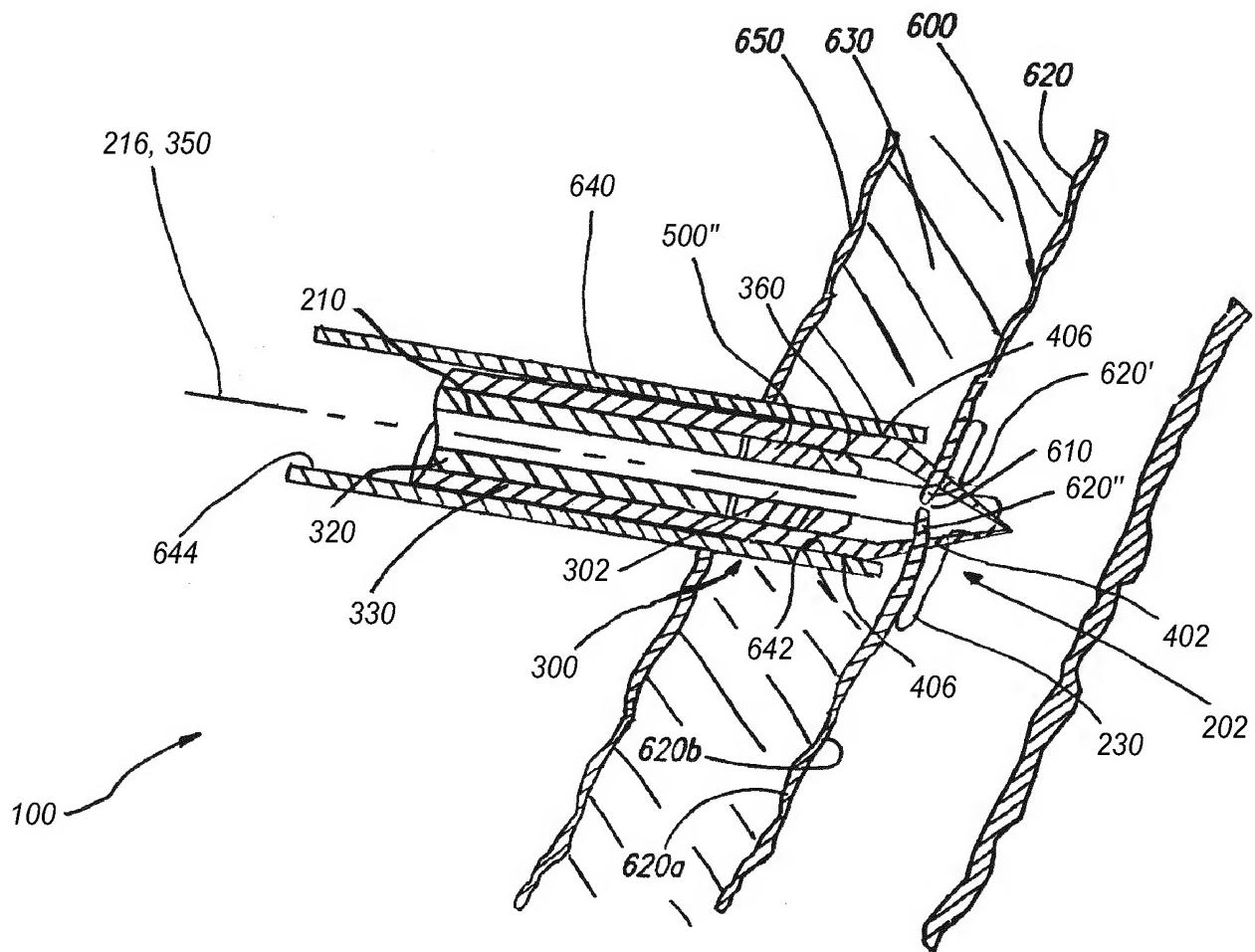


FIG. 8F

13 / 18

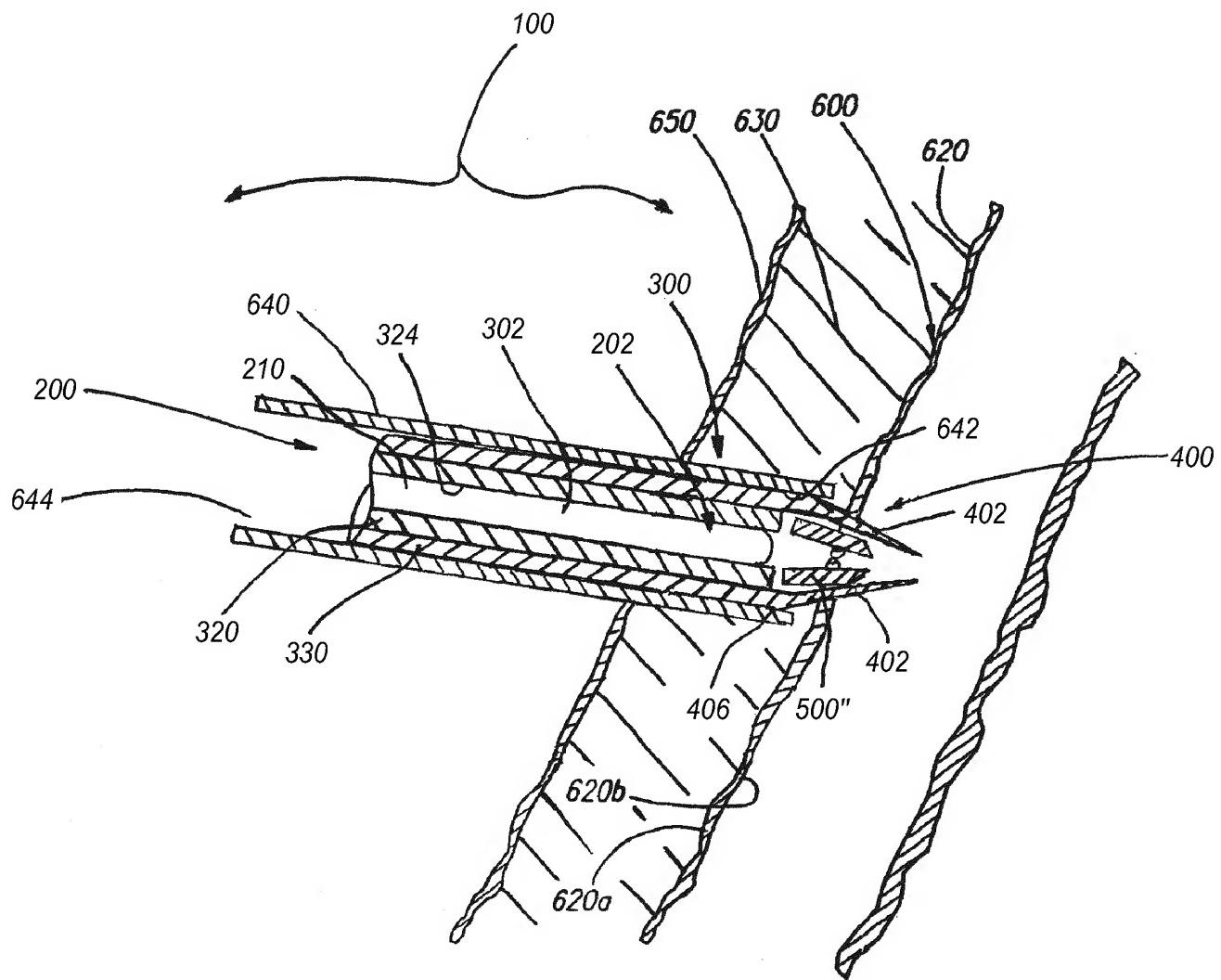


FIG. 8G

14 / 18

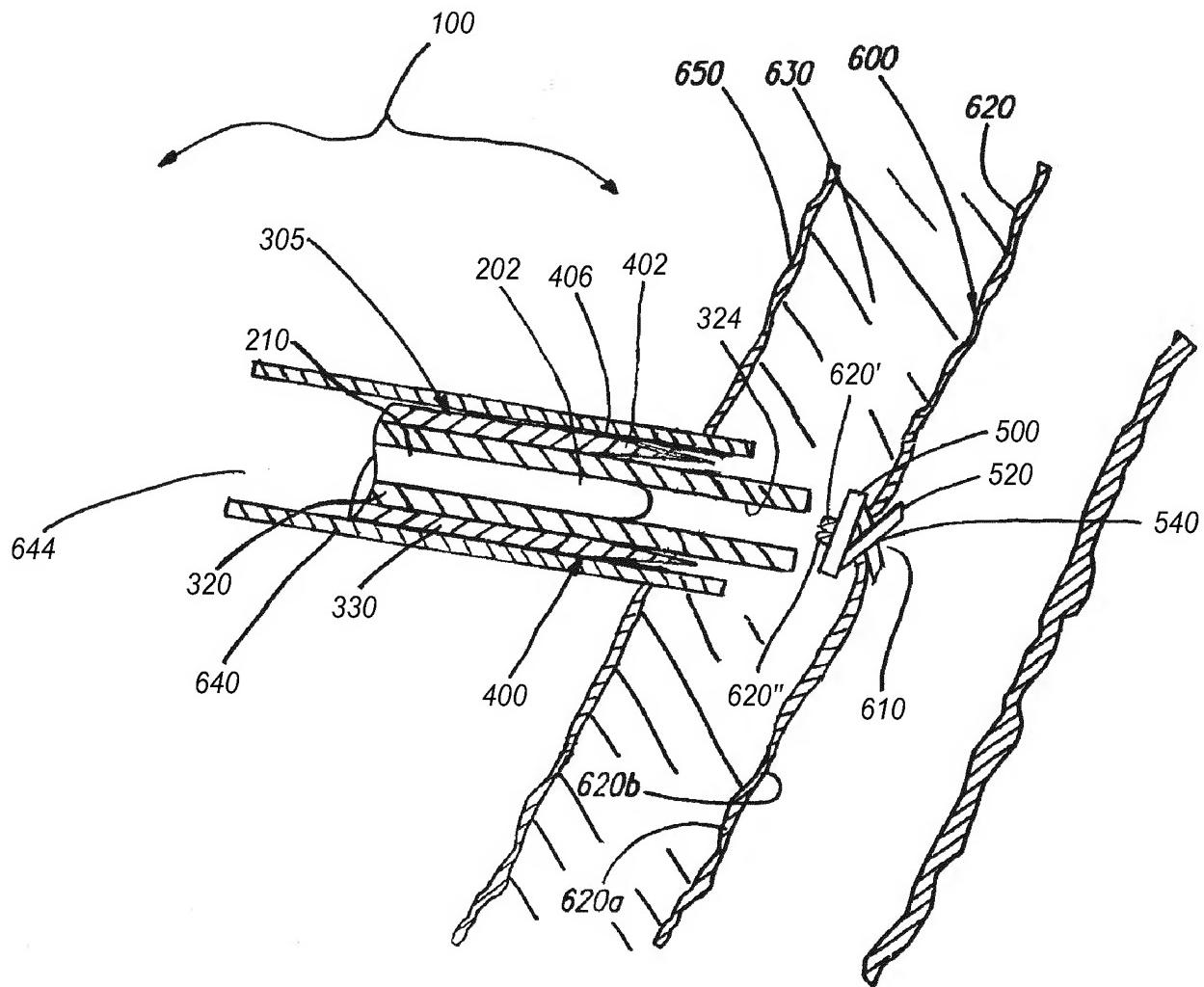


FIG.—8H

15 / 18

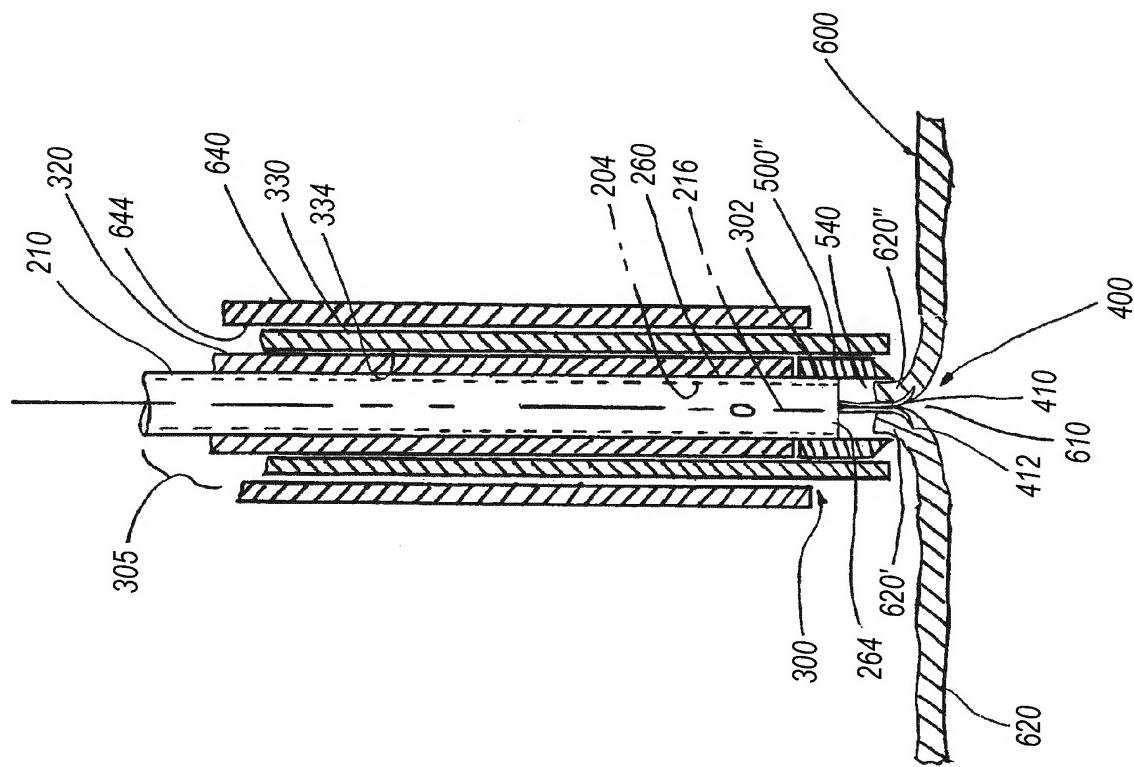


FIG. 10

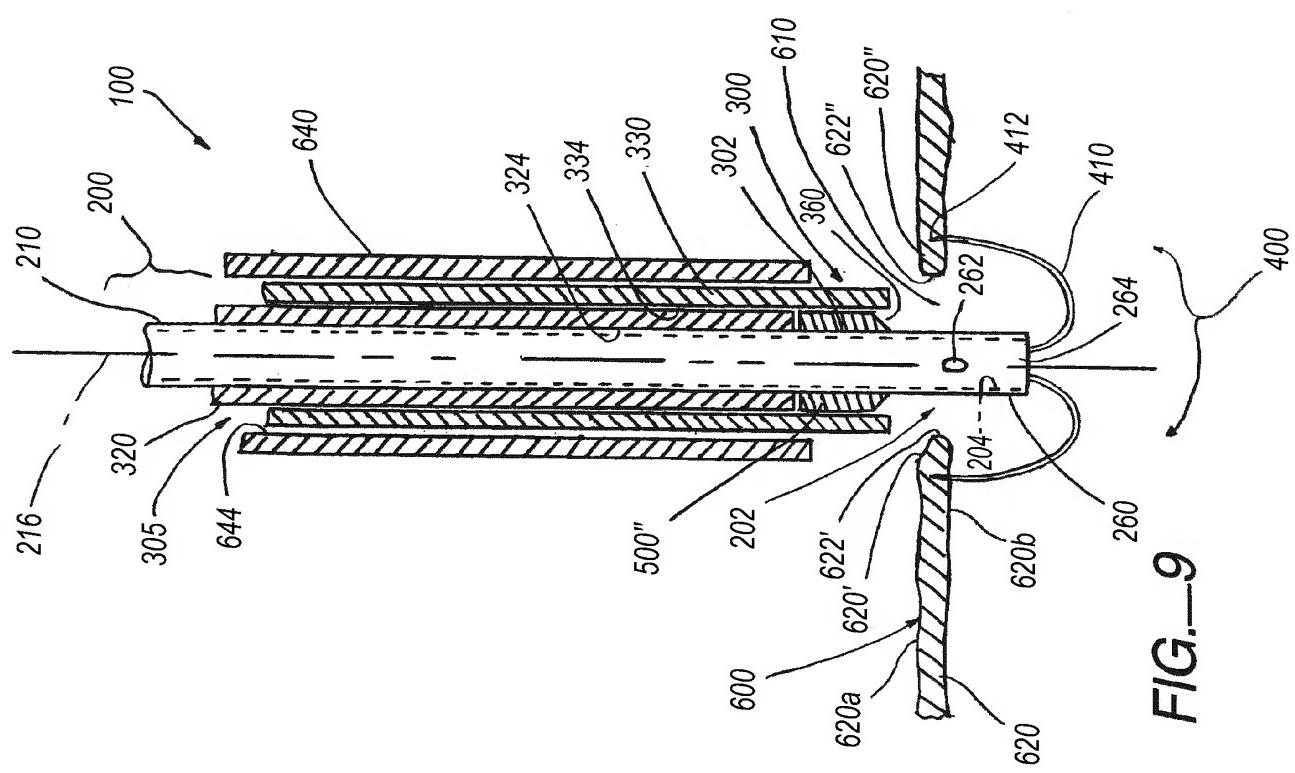


FIG. 9

16 / 18

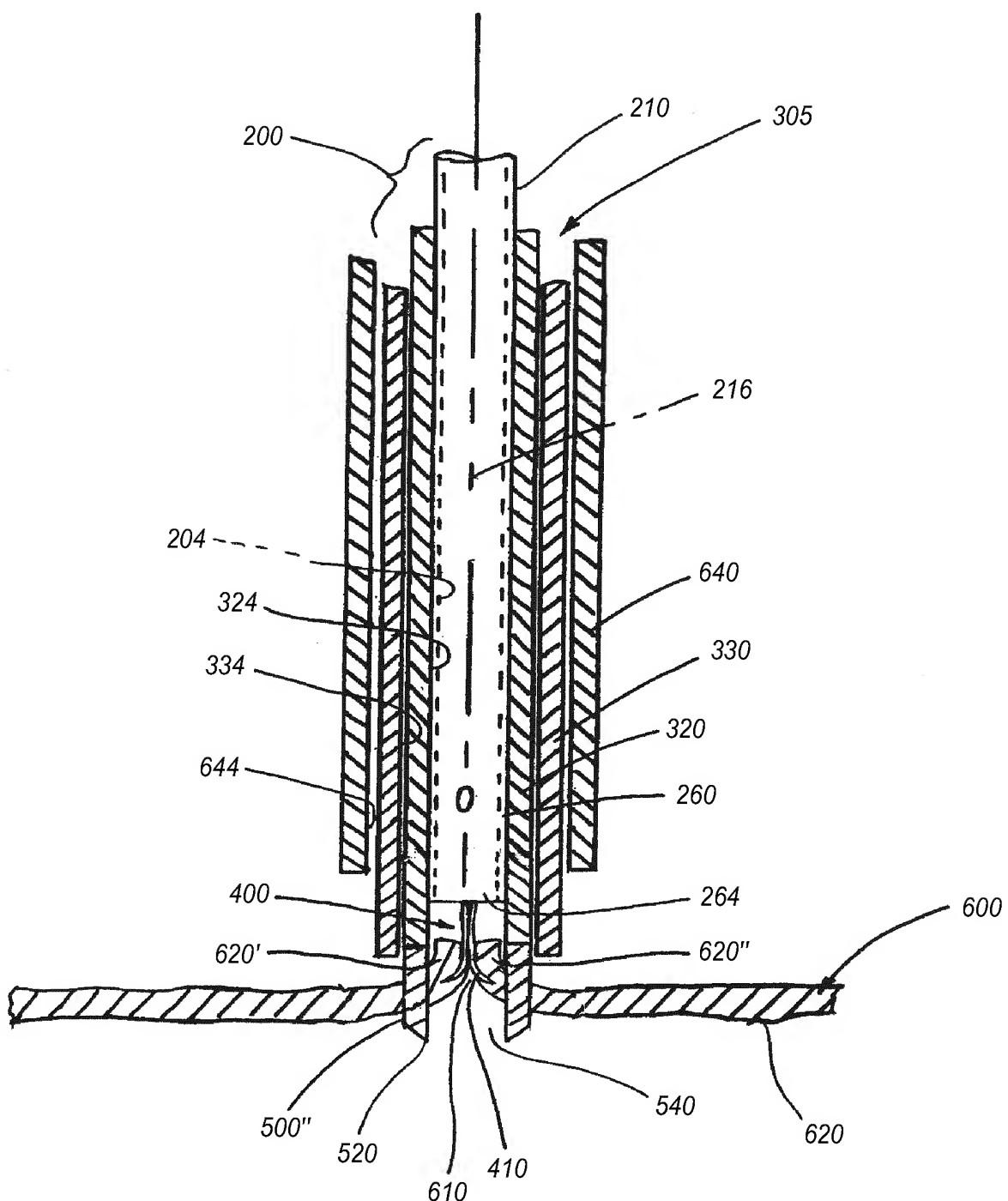
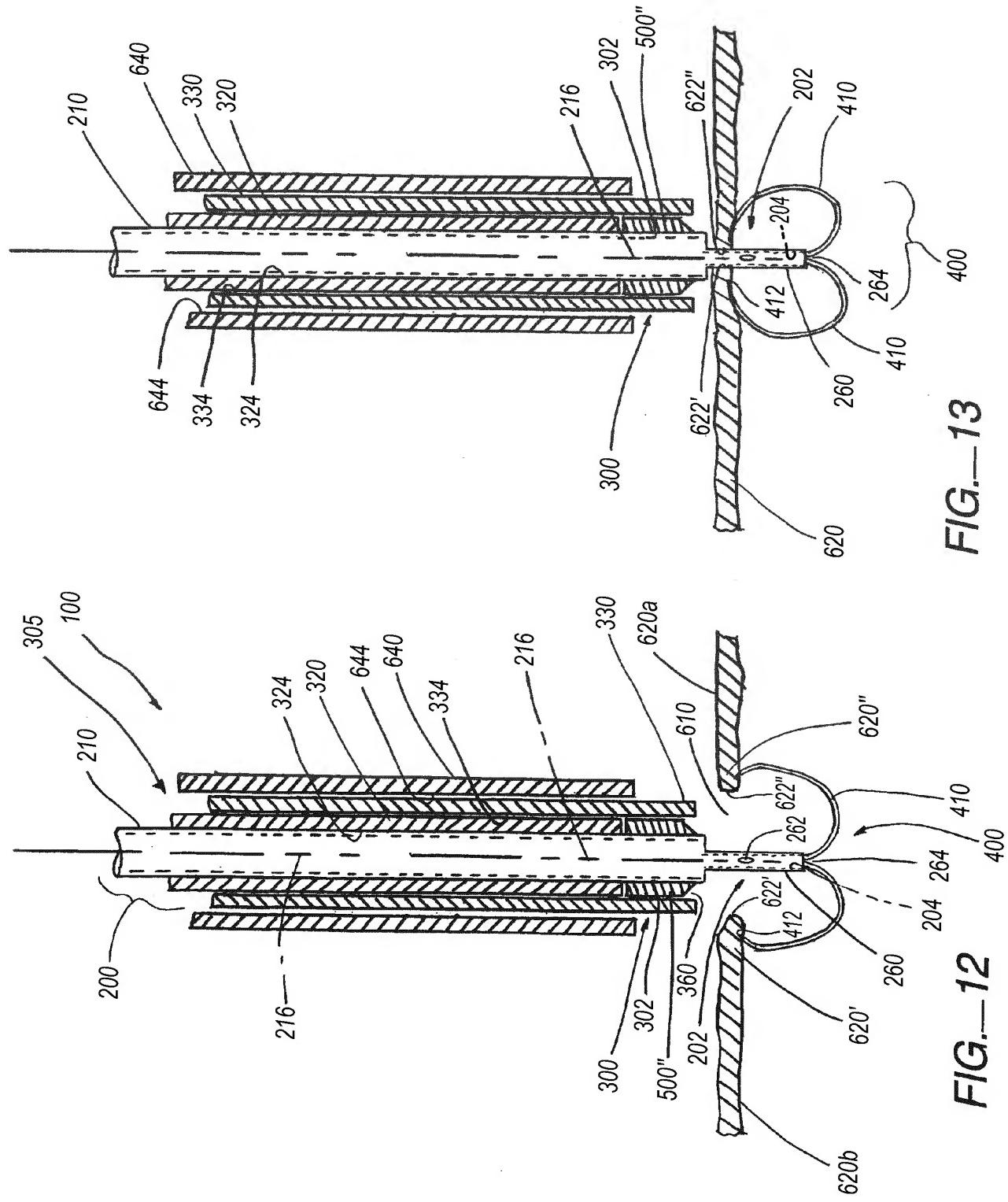
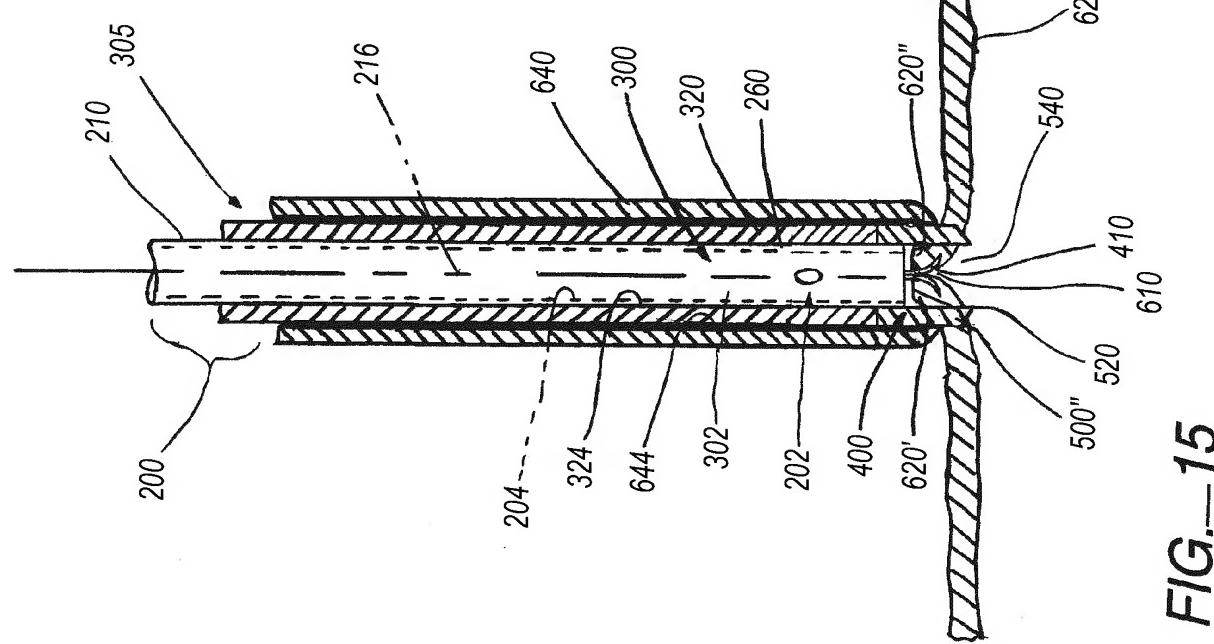
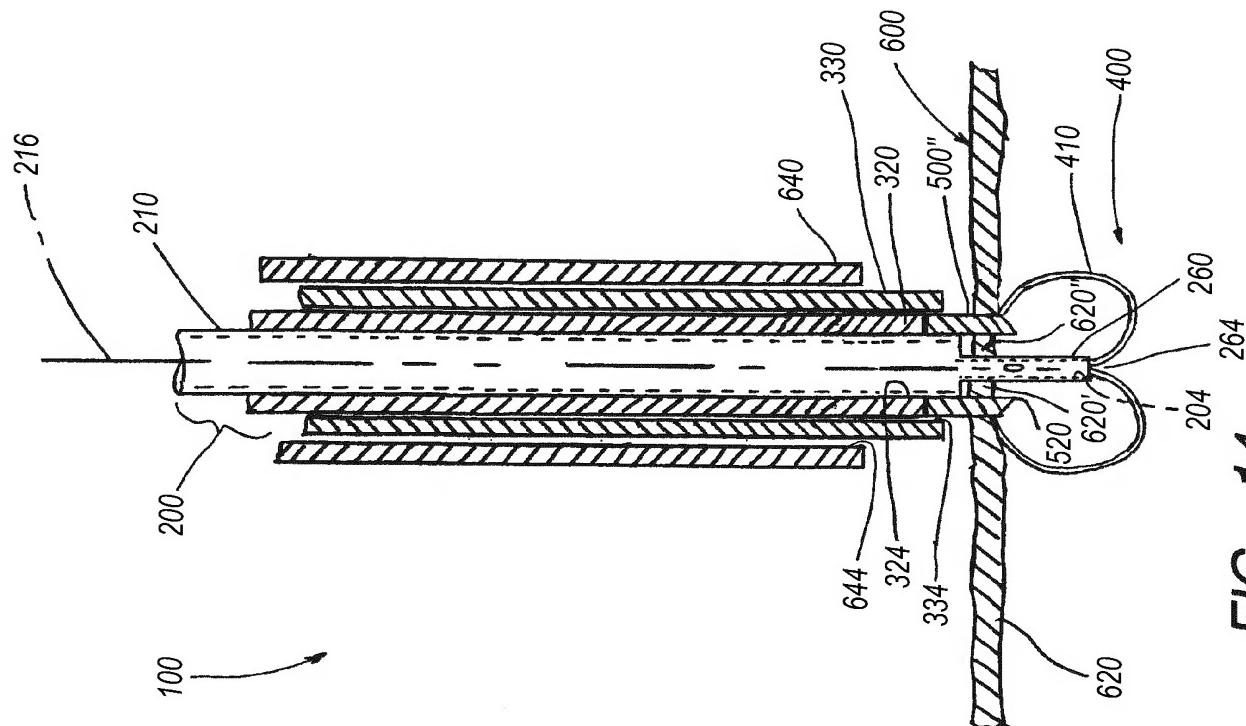


FIG.—11



18 / 18



## INTERNATIONAL SEARCH REPORT

International application No

PCT/US2007/078051

**A. CLASSIFICATION OF SUBJECT MATTER**  
 INV. A61B17/00 A61B17/068 A61B17/064

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**Minimum documentation searched (classification system followed by classification symbols)  
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category* | Citation of document, with indication, where appropriate, of the relevant passages   | Relevant to claim No. |
|-----------|--|-----------------------|
| A         | US 2004/153122 A1 (PALERMO THOMAS [US])<br>5 August 2004 (2004-08-05)<br>cited in the application<br>abstract; figure 8<br>----- | 1-19                  |

 Further documents are listed in the continuation of Box C. See patent family annex.

## \* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*&\* document member of the same patent family

Date of the actual completion of the International search

11 December 2007

Date of mailing of the international search report

19/12/2007

Name and mailing address of the ISA/  
 European Patent Office, P.B. 5818 Patentlaan 2  
 NL - 2280 HV Rijswijk  
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
 Fax: (+31-70) 340-3016

Authorized officer

Hansen, Soren

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2007/078051

## Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: 20–25 because they relate to subject matter not required to be searched by this Authority, namely:  
**Rule 39.1(iv) PCT – Method for treatment of the human or animal body by surgery**
2.  Claims Nos.: because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3.  Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3.  As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4.  No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No

PCT/US2007/078051

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|--|------------------|-------------------------|------------------|
| US 2004153122 A1                       | 05-08-2004 US    | 2004153123 A1           | 05-08-2004       |